

From: Wholley, David (FNIH) [T]
Sent: Wed, 18 Oct 2017 21:23:46 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: FW: New PPPs for pain meds and OUD treatment

All: As promised from my conversation on Monday with Janet Woodcock. Should these folks be invited to Friday's call? If so, should Rebecca be the one to let Bill Chin know? Thanks, David

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From: Hertz, Sharon H [REDACTED] (b) (6)]
Sent: Wednesday, October 18, 2017 4:59 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Winchell, Celia J (FDA/CDER) [REDACTED] (b) (6); Fields, Ellen (FDA/CDER) [REDACTED] (b) (6)
Subject: New PPPs for pain meds and OUD treatment

Hi,

After discussing this with Dr. Woodcock, I am reaching out to let you know that Ellen Fields will be participating as the primary representative for the new pain meds PPP and Celia Winchell for the OUD treatment PPP. Allison Lin will also be participating from our division.

Thank you,
Sharon

Sharon Hertz, MD
Division Director
Division of Anesthesia, Analgesia, and Addiction Products
FDA/CDER
HFD-170, WO 22, Rm [REDACTED] (b) (6)
10903 New Hampshire Ave.
Silver Spring, MD 20993

[REDACTED] (b) (6)
301 796-7413 Fax

From: Wholley, David (FNIH) [T]
Sent: Fri, 1 Dec 2017 14:07:56 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: FW: NYTimes.com: Gifts Tied to Opioid Sales Invite a Question: Should Museums Vet Donors?

distribute to team

Sent by rbalthaser@yahoo.com:

The New York Times



Gifts Tied to Opioid Sales Invite a Question: Should Museums Vet Donors?

BY COLIN MOYNIHAN

The issue of how museums raise their money has resurfaced in the case of the Sacklers, a family of philanthropists whose company developed OxyContin.

Or, copy and paste this URL into your browser: <https://nyti.ms/2kewSZC>

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From: Wholley, David (FNIH) [T]
Sent: Thu, 7 Dec 2017 00:20:53 +0000
To: Stein, Jack (NIH/NIDA) [E];Chin, Bill (Chin@phrma.org);Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: FW: Opioids F2F Meeting Attendees to Date
Attachments: Opioid F2F Attendee List as of 06Dec2017 (4PM).xls

All – for your information (and Jack, in at least two cases, your requested action), please see where we are as of 4PM today on ACCEPTED invitations to next week's face to face meeting. (b) (4)

(b) (4) We will no doubt get more confirmations before Monday. Based on Mike Biarnes's reckoning, the following is the list of companies that have yet to confirm that at least one of their members will attend. (b) (4)

(b) (4) Let us know if we have missed any company in particular or if you feel you can be of additional help.

(b) (4)

From: Wholley, David (FNIH) [T]
Sent: Thu, 5 Oct 2017 14:53:23 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]
Subject: FW: PACT

(b) (4)

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From: Engelman, Jeffrey [mailto:jeffrey.engelman@novartis.com]
Sent: Thursday, October 05, 2017 10:03 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: PACT

Hi David,

Please see below. We had a lot of internal discussion and you can see that we would like to officially participate as outlined in the email below.

I am very pleased that we will be able to help get this launched!

Perhaps we can touch base next week to discuss next steps

Jeff

Jeffrey Engelman, M.D., Ph.D.
Global Head of Oncology
Novartis Institutes for BioMedical Research

Executive Assistant: Anita Caulfield
anita.caulfield@novartis.com
(617)-871-8200

From: "Bradner, James" <james.bradner@novartis.com>
Date: Thursday, October 5, 2017 at 9:58 AM
To: "Collins, Francis (NIH/OD) [E]" (b) (6)

Cc: "Rammohan, Revathi" <revathi.rammohan@novartis.com>, "Brown, Scott" <scott.brown@novartis.com>, Jeffrey Engelman <jeffrey.engelman@novartis.com>, "Hammerman, Peter" <peter.hammerman@novartis.com>, "Dranoff, Glenn" <glenn.dranoff@novartis.com>, Lilli Petruzzelli <lilli.petruzzelli@novartis.com>, "Lockwood, Jeffrey" <jeffrey.lockwood@novartis.com>

Subject: PACT

francis.

thank you for the invitation to steer and now join the NIH-PACT program focused on cancer immunotherapy biomarker discovery. this week we assembled our cancer and institutional leadership (many cc'd here), to examine the clarified design principles emerging from the workstream and to assess alignment with our critical path in IO and cancer medicine. we applaud the effort to pull together so many leading institutions and scientists around this generational activity. we agree violently that the development of next-generation IO agents will require new measurements guiding use and explaining (in)activity. in this regard, we are well aligned with the program and would like to participate.

my sense is that there are important strategic details still to define, regarding scientific focus, institutions/scientific leaders involved, clarified and prioritized measurements. jeff, peter, glenn and lilli cc'd will surely have helpful guidance, should the PACT welcome insights at this pivotal stage. candidly, our principal interest remains connected to the safe harbor the PACT might provide for combination clinical trials of next-gen agents between companies. we would welcome a chance to work with peer institutions through the NIH network. but even with a focus on biomarker creation, curation and deployment, we are motivated to join. i defer to jeff to provide guidance as to how best and who best to contribute these and other guidance.

(b) (4)

finally, we are working hard to help you hit your deadline on the announcement and would like to be a party to the announcement. peter can join in DC at the national press club, if this invitation is still open and helpful.

thank you for the invitation, again, to join. we so admire the heroic work you continue to lead, orienting our government around this rarified moment in biomedicine, openly assembling diverse research communities, and always defending basic research.

please advise on next steps.

best - jay

--

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research

james.bradner[at]novartis.com

From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 13:55:12 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]
Subject: FW: Partnership to Accelerate Cancer Therapies (PACT)

(b) (4)

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From: (b) (4)
Sent: Tuesday, October 03, 2017 10:45 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E]
(b) (6)
Subject: Re: Partnership to Accelerate Cancer Therapies (PACT)

Francis

I will look into it ,check with our division heads and let you know
Best
Elias

Envoyé de mon iPhone

Le 3 oct. 2017 à 18:29, Collins, Francis (NIH/OD) [E] (b) (6) a écrit :

(b) (4)

<Updated PACT Executive Summary 092617.docx>

From: Wholley, David (FNIH) [T]
Sent: Tue, 3 Oct 2017 15:10:29 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: FW: Partnership to Accelerate Cancer Therapies
Attachments: Updated PACT Executive Summary 092617.docx

(b) (4)

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From: Wholley, David (FNIH) [T]
Sent: Tuesday, October 03, 2017 10:10 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Subject: Partnership to Accelerate Cancer Therapies

Dear (b) (4),

It has been a while since we spoke about this, but I wanted to ask you for a favor regarding another public-private partnership we have been developing: the Partnership to Accelerate Cancer Therapies (PACT). As you might recall, we've spent the last 15 months or so working with FNIH, FDA, and multiple pharmaceutical companies to plan a partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a \$160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (4) to expand the number of novel markers, assays, and types of data that can be developed.

(b) (4)

The driving factor is that FNIH now has 8-9 companies pledged to support PACT, and that with encouragement from the White House we have committed to hold an announcement at the National Press Club downtown on October 12 (modeled on the announcements held for the Biomarkers Consortium and AMP) (b) (4)

I have attached a 2-page summary of PACT for reference, but please let me know if you have any additional questions.

Warm regards, Francis

<Updated PACT Executive Summary 092617.docx>

From: Wholley, David (FNIH) [T]
Sent: Wed, 6 Dec 2017 01:18:56 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: FW: Proposed agenda for Opioids Partnership F2F next week

Thoughts? Happy to make changes. By the way, I don't think our budgeting segment is going to address actual estimates at this point—too early in most cases—but will rather discuss strategies for coming to such general estimations in the white paper writing process.

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, December 5, 2017 5:47 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Moscicki, Richard <rmoscicki@phrma.org>
Subject: RE: Proposed agenda for Opioids Partnership F2F next week

David, Two thoughts. First, on 12/13 you have scheduled a session entitled, "Focus Area B: Refinement and Budgeting." But there is not analogous session for Focus Area A. Second, I think you should let PhRMA join Francis in the Introduction to ensure the optics reflect the PPP. You don't even need to list either me or Rich but one of us should welcome everyone and particularly get a chance to thank the industry members for their participation. My two cents. Bill

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Tuesday, December 05, 2017 1:31 PM
To: Chin, Bill
Cc: Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: Proposed agenda for Opioids Partnership F2F next week

Bill, please see the attached, result of our conversations with the NIH group so far, but pending input from the co-chairs and finalization. Please let me know if anything looks amiss.
David

We've moved! Please find our new address below.

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From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 01:04:14 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: FW: slides

Correcting email address

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From: Wholley, David (FNIH) [T]
Sent: Monday, October 09, 2017 9:02 PM
To: Volkow, Nora (NIH/NIDA) [E] (b) (6) Francis Collins (b) (6)
Cc: Stein, Jack (NIH/NIDA) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: RE: slides

(b) (5)

David

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From: Volkow, Nora (NIH/NIDA) [E]
Sent: Monday, October 09, 2017 5:15 PM

To: Francis Collins [REDACTED] (b) (6)
Cc: Stein, Jack (NIH/NIDA) [E] [REDACTED] (b) (6); Wholley, David (FNIH) [T] <dwholley@fniih.org>; Volkow, Nora (NIH/NIDA) [E] [REDACTED] (b) (6)
Subject: Re: slides

Dear Francis

(b) (5)

(b) (5)

(b) (5) Thaks, nora

From: Jack Stein [REDACTED] (b) (6)
Date: Monday, October 9, 2017 at 8:10 AM
To: Nora Volkow [REDACTED] (b) (6)>
Subject: FW: slides

Nora -

(b) (5)

I am avail this afternoon or eve to call you if care to talk this thru.

Jack

From David -

Francis, as requested:

(b) (5)

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Sent with BlackBerry Work
(www.blackberry.com)

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Dec 2017 20:11:32 +0000
To: Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: Fw: Summary of the summit meeting
Attachments: FNIH PPP Update for BMAC final draft 12-20-17.www.docx

Fyi I will look at this and send back to Rich in an hour or so unless I see something that could cause concern.

Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Thursday, December 21, 2017 2:36 PM
To: Wholley, David (FNIH) [T]
Subject: Summary of the summit meeting

Hi David, attached are some minor changes in the document. If you are ok with them, we will send to BMAC after legal review. Rich.

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Dec 2017 23:17:24 +0000
To: Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: FW: Survey cover letter draft and remaining questions

Dear Francis and group:

As mentioned in Joe Menetski's note to Rebecca Baker below summarizing our call this morning with the Asset & Data Sharing Working Group co-chairs, several of the industry co-chairs in particular expressed concern about the length (as in number of rows) of the survey we'd be asking each company to fill out, even if prepopulated to some extent. One solution was to send the survey as an Excel worksheet with two tabs: A) one that includes rows for just the programs belonging to the particular company responding to the survey, which would be the primary information we would be seeking from them, and B) a second tab that contains all of the ~3000 or so rows in the current full worksheet, in case they have insights on other programs they wish to share. Several of the co-chairs briefly asserted that including opioids and NSAIDs in the list would be "useless" and provide a disincentive to companies to respond in areas that would be more fruitful for the collaborations we are seeking. The rest of the group seemed to agree broadly. There were no further specific comments as to sub-type or category of opioid or NSAID that should be excluded or more specific reasons for doing so. We repeated back to the group that what we should do is to leave opioids and NSAIDs in the general "TAB B" spreadsheet but exclude them from the company-specific "TAB A" section of the final survey, and the group confirmed that as their recommendation.

By the way this is not the first time we have heard this idea—the Asset Repurposing and Data Sharing Working Groups have asserted since the beginning of the process that there is an inverse relationship to the amount of data we seek in the survey and the prospect of getting a viable answer to our request from companies. There was even a brief discussion about this during the face to face meeting, though it apparently did not make it into the final discussion of key conclusions and action items. If there is indeed concern about removing opioids from TAB A of the survey, it might be useful middle ground if we can determine whether the concern is about removing any opioid program from TAB A or just some specific types of opioids.

Please let us know how you would like to handle as soon as possible.

Thanks, David

From: Menetski, Joseph (FNIH) [T]
Sent: Thursday, December 21, 2017 12:49 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: FW: Survey cover letter draft and remaining questions

Dear Rebecca,

Below are the results of today's discussion on the survey and the process for moving forward. David W has been read into this and can fill in any details that you may need to fill gaps.

Most of the meeting today was a discussion about writing assignments for the white paper, which will be provided by Michael B.

Best,

Joe

From: Menetski, Joseph (FNIH) [T]
Sent: Thursday, December 21, 2017 12:44 PM
To: 'Flores, Christopher [CONUS]' <CFlores2@its.jnj.com>; 'Dunlop, John' <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: 'Osman.cigeroglu@pfizer.com' <Osman.cigeroglu@pfizer.com>; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>
Subject: RE: Survey cover letter draft and remaining questions

Dear All,

Just recapping what I heard on the phone.

We will focus on getting the survey right, rather than getting it out prematurely in a unusable form.

To accomplish this, we will pilot the survey to several companies that are already involved in the partnership, but not currently involved in setting up the survey. Suggestions are; Pfizer, Lilly and Purdue. We will also send a survey to AZ, after John Dunlop has had a chance to contact an internal AZ acquaintance and prime them on the survey and the need.

Joe will generate excel files that contain tabs for 1) the entire list as it currently appears and 2) a company specific list that contains only programs from that request company. We will ask the company to update their programs in the company specific tab and also to provide any suggestions on programs that they are aware of in the full list.

We talked about removing the NSAIDs and opioids from the list, and I will remove them from the company specific list.

For the pilot, we should ask the partnership representatives to also provide their feedback on how the process of filling in the survey went (this may be best as a phone conversation).

Finally, I believe I heard that the pilot survey requests will be sent out after the first of the year. Suggested deadline of completion in 3 weeks after receipt of the survey.

Best regards,

Joe

From: Menetski, Joseph (FNIH) [T]
Sent: Thursday, December 21, 2017 9:09 AM
To: 'Flores, Christopher [CONUS]' <CFlores2@its.jnj.com>; Dunlop, John <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>
Subject: RE: Survey cover letter draft and remaining questions

Dear All,

Please find an updated version of the cover letter attached to this email. I have tried to incorporate your suggestion and comments. Please let me know if this sounds good enough to distribute widely?

Also, the asset repurposing co-chairs and Jack, have been added to the data sharing call today.

Along with a discussion on how we will get the white paper written, we will need to come to a resolution on how the survey is distributed. It is critical that this issue get resolved today.

We look forward to talking to you.

Best regards,

Joe

From: Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]
Sent: Wednesday, December 20, 2017 6:48 PM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Dunlop, John <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] <michael.oshinsky@nih.gov>; Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>
Subject: RE: Survey cover letter draft and remaining questions

Dear all,

With thanks to Joe for drafting this cover letter and apologies for the delay in responding here – I've just finished unburying myself from being out last week☺ – please find attached my tracked suggestions on top of Michael's version. Admittedly, there is a needle to thread here in terms of balancing the desire for brevity with the need to provide compelling information.

Otherwise, I notice that not all of the co-chairs for the Data Sharing/Asset Repurposing workstream have been invited to tomorrow's TC; and so, may I please ask Cheryl to remedy this.

Looking forward to bringing this forward with all of you,
Chris

From: Menetski, Joseph (FNIH) [T] [<mailto:jmenetski@fnih.org>]
Sent: Wednesday, December 20, 2017 8:50 AM
To: Dunlop, John <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Flores, Christopher [CONUS] <CFlores2@its.jni.com>; Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: Survey cover letter draft and remaining questions

John, Michael, Chris and Chris,

Given the last 2 emails on this subject, I think it might be a good idea to have a short TC to settle the issue of how we send out the table. I don't want to be confusing, but I also don't want to make it so cumbersome that the results will be unmanageable when we get them back from the companies.

Would you be available for a 30 min meeting today or tomorrow?

I am open from 10-11am and after 1:30 today. My time is trickier tomorrow, but I will rearrange it to get together. I see that we have a co-chair meeting tomorrow with John and Michael, but I think this is an issue that we need to settle before that (also, I think the plan for that meeting is to discuss writing the white paper).

With respect to "unidentified pharmacological activity", you are absolutely right, it is problematic. On occasion, this can be obtained from detective work, but this is a field that the company responsible for the program should be able to identify easily, which would be the best solution. Otherwise, we will just have to remove them from deeper analysis. Generally this annotation is found in the preclinical space, but can sometime remain into later stages of development.

Please respond with you availability to talk, I can modify the table, but just need your decision on how.

Best regards,

Joe

From: Dunlop, John [<mailto:jdunlop@amgen.com>]
Sent: Wednesday, December 20, 2017 8:33 AM
To: Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; cflores2@its.jni.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David

(FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>

Subject: RE: Survey cover letter draft and remaining questions

Joe

I'm afraid it has the opposite effect on me – too long and clunky. Maybe it's the way my brain is organized, or how it organizes things, but I'd prefer to see some additional formatting along the lines of separate tabs for pain-non-opioid, pain-opioid and addiction, e.g..

I also find 'unidentified pharmacological activity' to be problematic – in some cases there is a known pharmacology for the asset but its just not captured, while in other cases its truly not known – the latter is particularly problematic, requires additional level of detective work and low probability that there will be something behind that is exciting..

JD

From: Oshinsky, Michael (NIH/NINDS) [E] (b) (6)

Sent: Tuesday, December 19, 2017 1:25 PM

To: Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Dunlop, John <jdunlop@amgen.com>; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)

Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>

Subject: RE: Survey cover letter draft and remaining questions

Joe,

I have no problem with the length of the table, I think it's important to be inclusive of his many active and discontinued programs as possible.

Michael

Michael L. Oshinsky, Ph.D.

Program Director, Pain and Migraine

NINDS/NIH

6001 Executive Blvd, (b) (6), MSC 9521

Bethesda, MD 20892-9521

Rockville, MD 20852 (for UPS, FedEx etc.)

Tel (b) (6)

FAX 301 402 2060

Email (b) (6)

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, December 19, 2017 1:17 PM

To: Oshinsky, Michael (NIH/NINDS) [E] (b) (6); jdunlop@amgen.com; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)

Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>

Subject: RE: Survey cover letter draft and remaining questions

Thank you for the comments on the cover letter.

Could everyone please comment on the length of the table and excluding entries. We need to have that resolved before we send anything to a broader group.

Thank you,

Joe

From: Oshinsky, Michael (NIH/NINDS) [E]
Sent: Tuesday, December 19, 2017 10:20 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; jdunlop@amgen.com; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: RE: Survey cover letter draft and remaining questions

Joe,

Thank you for putting together this first draft. Here are my edits on the text for the email.

I would also like to suggest adding two fields to the contact information for a total of three fields. I am afraid that the field may be filled with a name only which is not as useful as the full contact information. The field will be: 1) contact name; 2) contact phone; 3) contact email.

Michael

Michael L. Oshinsky, Ph.D.
Program Director, Pain and Migraine
NINDS/NIH
6001 Executive Blvd, (b) (6), MSC 9521
Bethesda, MD 20892-9521
Rockville, MD 20852 (for UPS, FedEx etc.)

Tel (b) (6)

FAX 301 402 2060

Email (b) (6)

From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, December 19, 2017 8:25 AM
To: Oshinsky, Michael (NIH/NINDS) [E] (b) (6); jdunlop@amgen.com; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)
Cc: Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: Survey cover letter draft and remaining questions

Dear Asset and Data Sharing Co-chairs,

FNIH has put together a draft of a cover letter to request participation in filling in the survey. This is an initial draft, so please modify and comment so that we have the best chance of getting the information we need to be successful. I am providing the draft as a word document to allow changes to be tracked.

We have identified several issues that did not appear to be fully resolved at the face to face meeting. We need to make decisions on these before we distribute this survey request.

- We need to confirm that the columns included in the table are the right fields for the initial request.
- There was discussion that the initial prepopulated table should be reduced to only those programs that are likely to be of interest, or are only associated with companies currently in the development phase of the partnership. I do not remember (or have notes) that suggest we came to a definitive decision on this issue.

I have attached both the cover letter draft and the current survey to this email. We will not send out the survey until we have answers to the issues regarding the table and you have provided comments and modifications to the cover letter.

We are on a very short timeline, so please respond by the end of business tomorrow, Wednesday the 20th, so we can get this out by the end of the week. If you think we need a short teleconference to discuss, let me know and I will put together a meeting.

Best regards,

Joe

We've moved! Please find our new address below.

Joseph P. Menetski, Ph.D.

Deputy Director of Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6596

fnih.org

11400 Rockville Pike Suite 600 North Bethesda MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Fri, 22 Dec 2017 18:18:37 +0000
To: john.dunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E]; Flores, Christopher [CONUS]; Colvis, Christine (NIH/NCATS) [E]
Cc: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: FW: Survey cover letter draft and remaining questions

Dear Asset & Data Sharing Co-Chairs:

We had an update call yesterday afternoon with Francis Collins, Nora Volkow, Walter Koroshetz and others to update them where things stand with the opioid partnership effort, including the survey. We mentioned that on yesterday morning's co-chair call with Joe Menetski and Mike Biarnes the suggestion was made by you all to remove opioids and NSAIDs from the individual program tabs we are asking the companies to look at as primary entries for the survey, in the interest of reducing as much as possible the amount of prepopulated rows the companies need to consider and improve POS. (I believe it was decided to leave this information in the second tab that lists all entries.)

This elicited a little concern from the group, particularly Nora, because while the value of opioids as analgesics may be lacking the feeling is they might have some relevance to opioid addiction or overdose reversal. This has in fact been discussed on some of the recent phone calls NIDA has been having with the Working Group addressing focused medications development. Would it be possible to find a way do you think to ask companies about broad categories of antagonists or diverse variety of agonists if the company feels they could be of particular value for addiction or overdose? I have copied Nora and some others here: please let us, and particularly Joe Menetski, know how we might best resolve this so we can send the survey out as soon as possible after the New Year—or, if you think it requires further discussion let us know and we can try to set up a brief conversation among the relevant individuals.

Thanks,
David

From: Wholley, David (FNIH) [T]
Sent: Mon, 2 Oct 2017 18:07:42 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: FW: Update on PACT?

(b) (4), (b) (5)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: (b) (4)
Sent: Monday, October 02, 2017 12:34 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: (b) (4); Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: Update on PACT?

David,

(b) (4)

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]
Sent: Monday, October 02, 2017 9:45 AM
To: (b) (4)
Cc: Adam, Stacey (FNIH) [T]
Subject: RE: Update on PACT?

(b) (4), (b) (5)

(b) (4), (b) (5) NIH is moving forward with their communications and announcement plan for the 12th, and are asking me for status.

Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: (b) (4)
Sent: Wednesday, September 27, 2017 3:28 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: Update on PACT?

David,

(b) (4)

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]
Sent: Tuesday, September 26, 2017 4:20 PM
To: (b) (4)
Cc: Adam, Stacey (FNIH) [T]
Subject: RE: Update on PACT?

(b) (4)

The announcement of the launch of the Partnership to Advance Cancer Therapies (PACT) is almost certainly going to be on October 12, at the National Press Club. (b) (4)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: [REDACTED] (b) (4)
Sent: Monday, September 18, 2017 5:49 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: [REDACTED] (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: Update on PACT?

David,

Sorry for the delayed reply [REDACTED] (b) (6)

(b) (4)

Sent from my iPhone

On Sep 15, 2017, at 2:47 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

(b) (4)

Please let me know, or any additional information I can supply you.

Best regards,
David Wholley

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Friday, September 08, 2017 10:21 AM
To: [REDACTED] (b) (4)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Update on PACT?

(b) (4)

(b) (4) Thank you,

David Wholley

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Wed, 6 Dec 2017 22:47:12 +0000
To: Volkow, Nora (NIH/NIDA) [E]; Collins, Francis (NIH/OD) [E]; Chin, Bill (Chin@phrma.org); Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: FW: Update on Pre-population of the Program survey
Attachments: Survey data collection table.xlsx

Just a quick interim heads up on work done and where it stands...

From: Menetski, Joseph (FNIH) [T]
Sent: Wednesday, December 6, 2017 4:05 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Update on Pre-population of the Program survey

Dear David,

I have been working on pre-populating the survey with the fields from Pain Programs that are active now, or have been active in the last 10 years. In filling out the survey fields, I have made a couple observations.

1. The Survey is 2935 rows long with pre-populated data. I have included all programs that were in any stage of development of the past 10 years, as requested by the team. The data can be sorted by highest level of development observed in the database.
2. There are several fields in the survey that seem to be focused on Study-level data. I have generated a table of the fields in the survey to highlight my concern (Attached to this email). In addition, I have added to that table, which fields are prepopulated, which can be populated with some hands-on effort and which can only be filled in with input from the company developing the drug.

I think this information may be of interest to the teams involved.

Best regards,

Joe

We've moved! Please find our new address below.

Joseph P. Menetski, Ph.D.

Deputy Director of Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6596

fnih.org

11400 Rockville Pike Suite 600 North Bethesda MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 16:34:48 +0000
To: Collins, Francis (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]; Burklow, John (NIH/OD) [E]
Subject: Gilead

Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 17:05:51 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]; Burklow, John (NIH/OD) [E]
Subject: Gilead

Dear All:

Looks like we have some more work for Renate (sorry about that!) Gilead called me this morning to let me know they are joining PACT. Maria Freire had spoken about PACT with Steve Paul, our Board Chairman, and it turns out Steve had recently met Gilead's CEO, John Milligan, at a venture meeting. Steve emailed John, and I followed that up with Chuck Clapton, their government relations representative, at the Friends of Cancer Research meeting last Wednesday evening. This is new territory for Gilead, by the way, as they have not been involved in many partnerships of this kind. No doubt Gilead's purchase of Kite Pharma in August played a big role in rekindling their interest in PACT.

Renate, given the timing the most likely participant in Thursday's meeting will be Kacy Hutchison, their VP North America Government Relations, but she will confirm that this afternoon and is also getting me the name of a communications contact.

So we now have eleven companies, and just really need to hear back definitively from Sanofi.
Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Tue, 19 Sep 2017 17:47:39 +0000
To: Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]
Cc: Menetski, Joseph (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]
Subject: FW: Pain Drug development analysis
Attachments: Pain programs from the last 10 years.pptx

Hi All—

Please see attached just FYI some 'competitive intelligence' on industry drug programs in pain over the last 10 years, from our Deputy Director of Research Partnerships, Joe Menetski. He used a competitive intelligence database that we have access to called PharmaProjects, which Joe says is probably one of the better databases Joe has used in his previous experience in competitive intelligence at Merck.

I guess the bottom line, which you no doubt know, is that industry—particularly Pfizer and Merck--has interrogated a broad variety of mechanisms. Joe would be happy to try to provide more details from analysis of the database if you have questions of particular interest.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 20:00:15 +0000
To: Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: FW: Partnership for Accelerating Cancer Therapies (PACT)

FYI I asked for a formal email of commitment from Gilead. Here it is.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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-----Original Message-----

From: Kacy Hutchison [<mailto:Kacy.Hutchison@gilead.com>]
Sent: Tuesday, October 10, 2017 3:24 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wolf-Rodda, Julie (FNIH) [T] <jwolf-rodde@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Gregg Alton <Gregg.Alton@gilead.com>; Amy Flood <Amy.Flood@gilead.com>; Chuck Clapton <Chuck.Clapton@gilead.com>
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Hi David -

Thank you for the call today. On behalf of Gilead Sciences, we are pleased to support the NIH Foundation and your invitation to join the Partnership for Accelerating Cancer Therapies (PACT). Per your request of industry partners, (b) (4), (b) (5) as a multi-year contribution as part of your public/private collaboration to help fund the development of standardized biomarkers and assays for trials of new cancer immunotherapies and combination therapies.

We look forward to future discussions. I'll be back in touch in regard to the information you requested in preparation for the announcement on Thursday shortly.

Sincerely,

Kacy

Kacy Hutchison
Vice President, North America Government Affairs Gilead Sciences, Inc.
333 Lakeside Drive,
Foster City, CA 94404
(O) 650-522-1831
(C) (b) (6)

-----Original Message-----

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]

Sent: Tuesday, October 10, 2017 1:07 PM
To: Kacy Hutchison; Adam, Stacey (FNIH) [T]
Cc: Wolf-Rodda, Julie (FNIH) [T]
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Stacey, can you please send Kacy a template (b) (4) Thanks

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Wed, 25 Oct 2017 19:19:14 +0000
To: Collins, Francis (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Lowy, Douglas (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]
Subject: FW: Partnership for Accelerating Cancer Therapies (PACT)
Attachments: (b) (4)

FYI. Perhaps we can discuss this tomorrow.

-----Original Message-----

From: Chuck Clapton [mailto:Chuck.Clapton@gilead.com]
Sent: Wednesday, October 25, 2017 10:58 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

David,

Thanks again for speaking last week (b) (4)
(b) (4)
(b) (4) and I would be grateful for any assistance you can provide in helping us navigate this process. Thanks again for all of your assistance.

Chuck

-----Original Message-----

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Wednesday, October 18, 2017 9:30 AM
To: Chuck Clapton
Subject: Re: Partnership for Accelerating Cancer Therapies (PACT)

It may need to be this afternoon but I will call.

Sent from my BlackBerry 10 smartphone.

Original Message

From: Chuck Clapton
Sent: Wednesday, October 18, 2017 8:58 AM
To: Wholley, David (FNIH) [T]
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

David -- thanks for getting back to me. You can call any time it would be convenient for you -- my cell is (b) (6)
(b) (6) Thanks

-----Original Message-----

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Tuesday, October 17, 2017 12:13 PM
To: Chuck Clapton
Cc: Adam, Stacey (FNIH) [T]; Melencio, Cheryl (FNIH) [T]
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Sure, Chuck, please let me know when you'd like to speak and number at which you can be reached.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnihi.org

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-----Original Message-----

From: Chuck Clapton [<mailto:Chuck.Clapton@gilead.com>]
Sent: Tuesday, October 17, 2017 9:59 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

David,
Is there any chance you might be around anytime today for a call? Just want to follow up on a couple of questions on exec comm and joint steering committee. Thanks Chuck

Direct (b) (6), cell (b) (6)

-----Original Message-----

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnihi.org>]
Sent: Tuesday, October 10, 2017 11:45 AM
To: Chuck Clapton
Subject: Re: Partnership for Accelerating Cancer Therapies (PACT)

Can you speak now? If not I should be available again in 30 minutes.

Sent from my BlackBerry 10 smartphone.

Original Message

From: Wholley, David (FNIH) [T]
Sent: Tuesday, October 10, 2017 11:23 AM
To: Chuck Clapton
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Yes, I should be jumping off the train in Union Station within the next 15-20 minutes and can give you a call from my cell. What number should I use to reach you?

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnihi.org

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-----Original Message-----

From: Chuck Clapton [<mailto:Chuck.Clapton@gilead.com>]
Sent: Tuesday, October 10, 2017 11:01 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Subject: Re: Partnership for Accelerating Cancer Therapies (PACT)

David,
Do you have any time within the next hour for a quick call? Thanks Chuck

Sent from my iPhone

On Oct 10, 2017, at 8:21 AM, Wholley, David (FNIH) [T] <dwholley@fnih.org<mailto:dwholley@fnih.org>> wrote:

Hi Chuck, just checking in to see if there has been any update.
Let me know if we can be of any help.

Sent from my BlackBerry 10 smartphone.
From: Chuck Clapton
Sent: Friday, October 6, 2017 11:05 AM
To: Wholley, David (FNIH) [T]
Cc: Melencio, Cheryl (FNIH) [T]
Subject: RE: Partnership for Accelerating Cancer Therapies (PACT)

Thanks David. I've sent this around to a group of our senior execs and will get back to you asap.

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]
Sent: Thursday, October 05, 2017 11:20 AM
To: Chuck Clapton
Cc: Melencio, Cheryl (FNIH) [T]
Subject: FW: Partnership for Accelerating Cancer Therapies (PACT)

Chuck - great to meet you last night, and thank you for your offer to help with communicating to John Milligan regarding PACT. Below is the email that our Board Chairman, Steve Paul, had our assistant send to John on his behalf. Please let me know if I can be of any further assistance.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org<www.fnih.org>

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From: Melencio, Cheryl (FNIH) [T]
Sent: Tuesday, October 03, 2017 11:55 AM
To: John.Milligan@gilead.com<mailto:John.Milligan@gilead.com>
Cc: Steven Paul <steve@thirdrockventures.com<mailto:steve@thirdrockventures.com>>; Wholley, David (FNIH) [T] <dwholley@fnih.org<mailto:dwholley@fnih.org>>
Subject: Partnership for Accelerating Cancer Therapies (PACT)

Dear Dr. Milligan:

On behalf of Dr. Steven Paul, Chairman of the Board, Foundation for the National Institutes of Health, please find attached letter.

Thank you.

Cheryl Melencio

Cheryl Melencio
Executive Assistant, Research Partnerships Foundation for the National Institutes of Health

(301) 402-4970
fnihi.org<www.fnihi.org>

The FNIH is the #1 ranked biomedical research organization & earned a 4-star rating from Charity Navigator<<https://www.charitynavigator.org/index.cfm?bay=search.summary&orgid=6244>>.

From: Wholley, David (FNIH) [T]
Sent: Mon, 9 Oct 2017 14:59:49 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Myles, Renate (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Meltzer, Abbey (FNIH) [T]
Subject: FW: Partnership to Accelerate Cancer Therapies (PACT)

(b) (4)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: (b) (4)
Sent: Monday, October 09, 2017 10:39 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: (b) (4)
Subject: Re: Partnership to Accelerate Cancer Therapies (PACT)

David

(b) (4)

(b) (4)

(b) (4)

Best regards,

Dave

On Oct 9, 2017, at 5:47 AM, Wholley, David (FNIH) [T] <dwholley@fnihi.org> wrote:

I will call you a 730 PT

Sent from my BlackBerry 10 smartphone.

From: (b) (4)
Sent: Sunday, October 8, 2017 11:18 PM
To: Wholley, David (FNIH) [T]
Cc: (b) (4); Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: Re: Partnership to Accelerate Cancer Therapies (PACT)

Hi David,

Any time between 7:30-9 PT would be good, if you are available.

Please call my cell phone: (b) (6)

Look forward to talking to you -

(b) (4)

On Oct 8, 2017, at 8:01 PM, Wholley, David (FNIH) [T] <dwholley@fnihi.org> wrote:

Hi David, is there a good time for me to call you tomorrow?

Sent from my BlackBerry 10 smartphone.

From: (b) (4)
Sent: Sunday, October 8, 2017 6:10 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; (b) (4)
Subject: Re: Partnership to Accelerate Cancer Therapies (PACT)

Dear Francis,

(b) (4)

On Oct 2, 2017, at 2:38 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear (b) (4),

I wanted to give you an update on the Partnership to Accelerate Cancer Therapies (PACT). As you may recall NIH worked with FNIH, FDA, and 14 pharmaceutical companies (b) (4) earlier this year to plan a public-private partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a \$160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (4) to expand the number of novel markers, assays, and types of data that can be developed.

(b) (4)

(b) (4) As a result, we now have eight companies pledged to support PACT, and will be holding an announcement at the National Press Club here in Washington on October 12 with all of the participants.

(b) (4)

(b) (4) Might you be willing to reconsider joining PACT, given where things now stand? It would be great to know before Oct. 12th so we can include you in the planning for the announcement.

(b) (4)

Warm regards, Francis

<Updated PACT Executive Summary 092617.docx>

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 18:59:42 +0000
To: Myles, Renate (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]
Subject: [REDACTED] (b) (4)
Importance: High

[REDACTED] (b) (4)

Please let me know if I may be of further assistance. David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]
Sent: Thu, 14 Dec 2017 19:14:58 +0000
To: Collins, Francis (NIH/OD) [E];Dolsten, Mikael;Hodes, Richard (NIH/NIA) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lifton, Richard;Lundberg, Jan;Rodgers, Griffin (NIH/NIDDK) [E];Stoffels, Paul;Tabak, Lawrence (NIH/OD) [E];Terry, Sharon MA;Wholley, David (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collier, David;Fischer, Tanya;Hodge, Martin;Ryan, Laurie (NIH/NIA) [E];Smith, Philip (NIH/NIDDK) [E];Sutherland, Margaret (NIH/NINDS) [E];Thomas, Melissa;Ehlers, Michael;Erion, Mark;Hait, Bill;Lepore, John;Li, Min;Lynch, Thomas;Miletich, Joseph;Moscicki, Rich;Plump, Andrew;Sullivan, Jim;Vessey, Rupert;Woodcock, Janet (FDA/CDER);Zerhouni, Elias;Patrick.Cullinan@Takeda.com;Li, Min;Hargreaves, Richard;Koemeter-Cox, Andrew;Moscicki, Rich;tsherer
Cc: Alesci, Salvatore;Carrillo, Maria;Collins, Mary;Eakin, Guy;Fillit, Howard;Goldmuntz, Ellen (NIH/NIAID) [E];Sheri Grabus;Hanrahan, Leslie;Hargreaves, Richard;Hendrix, James;Lappin, Debra;List, James;Marchiolo, Eryn;Jennifer McCulley;Pragnell, Marlon;Rotrosen, Daniel (NIH/NIAID) [E];tsherer;Tarrant, Teresa;Canet-Aviles, Rosa (FNIH) [T];Gadbois, Ellen (NIH/OD) [E];Sheri Grabus;Hoffmann, Steve (FNIH) [T];Kamphaus, Tania (FNIH) [T];tkerere@iqsolutions.com;Jennifer McCulley;Menetski, Joseph (FNIH) [T];Paltoo, Dina (NIH/OD) [E];Serrate-Sztejn, Susana (NIH/NIAMS) [E];Singh, Jyoti (NIH/OD) [E];Vardanian, Lilit (FNIH) [T]
Subject: MATERIALS for AMP Extended Executive Committee Teleconference December 15, 2017
Attachments: AMP Extended EC 12-15-2017 FINAL.pdf, 2017_06_30_AMP EEC teleconference final draft clean.pdf
Importance: Low

Dear AMP Extended Executive Committee members:

Attached are the materials for our call **from 7:00AM to 8:30AM Eastern U.S. Time this Friday, December 15:**

1. An Adobe.pdf document of the slide deck that will be used to guide our discussions during the meeting
2. An Adobe .pdf document containing the draft minutes from our June 30, 2017 AMP EEC call.

Call-in information is contained in the Microsoft Outlook calendar invitation you received for this meeting, but is repeated below. On behalf of the EEC co-chairs, Francis Collins and Mikael Dolsten, I look forward to an efficient and productive discussion.

[Join WebEx meeting](#)

Meeting number (access code): (b) (6)
(b) (6) vNpnSWe9

[Join by phone](#)

(b) (6) Call-in toll number (US/Canada)
[Global call-in numbers](#)

[Can't join the meeting?](#)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
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fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

We've moved! Please find our new address below.

Cheryl Melencio
Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
(301) 402-4970
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from [Charity Navigator](#).

Accelerating Medicines Partnership

Extended Executive Committee Update #7

15 December 2017



NIH - 001



Accelerating Medicines Partnership Type 2 Diabetes

Phil Smith, NIDDK

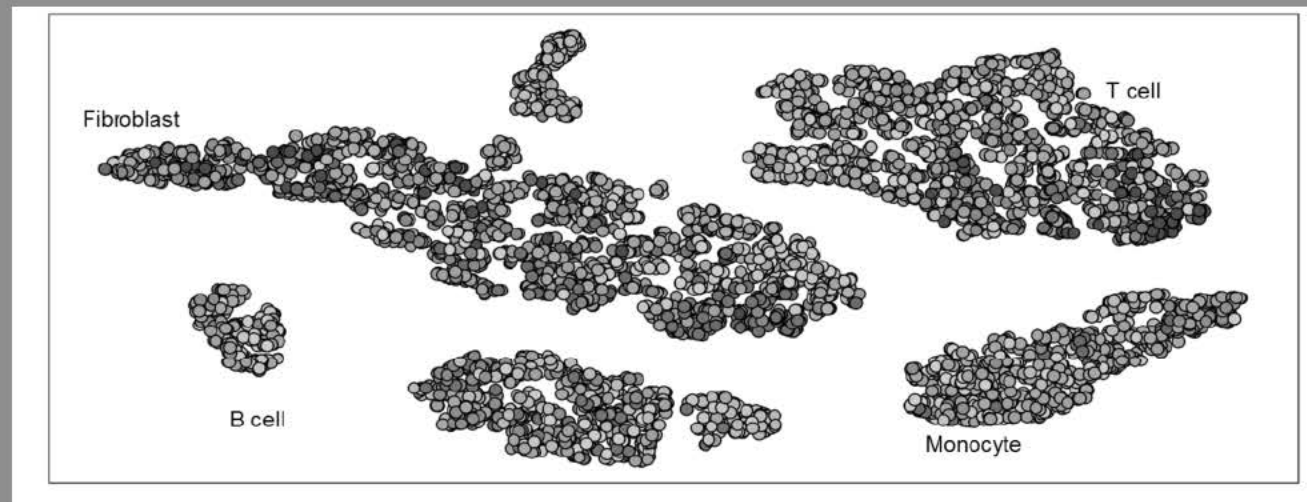
(b) (4)



NIH - 001



Accelerating Medicines Partnership RA/SLE



Bob Carter, NIAMS

(b) (4)



FNIH

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National Institutes of Health

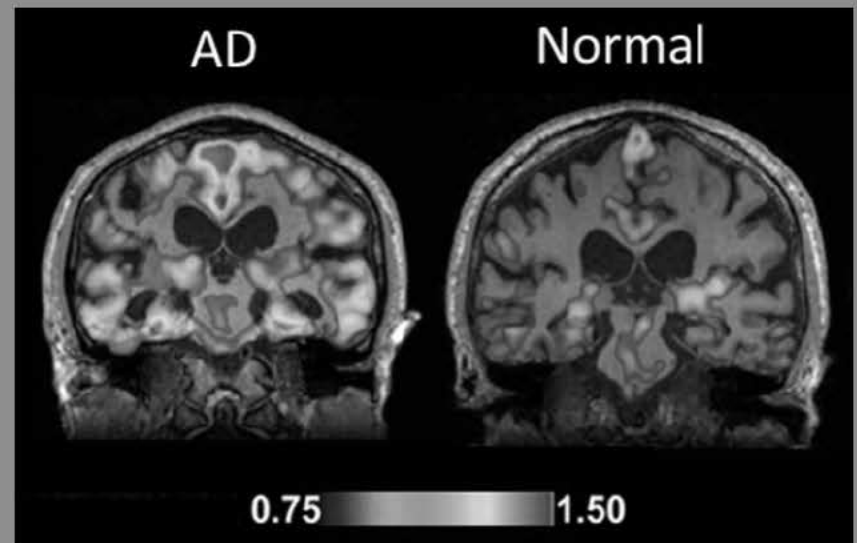
NIH - 001909



Accelerating Medicines Partnership Alzheimer's Disease

Laurie Ryan, NIA

(b) (4)



FNIH

Foundation for the
National Institutes of Health

NIH - 001927



Program Development

Marg Sutherland, NINDS



NIH - 001946



■ **Next Meeting:**

- AMP Extended Executive Committee: June 29

Backup Slides

**Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Extended Executive Committee (EEC)
Teleconference Meeting Minutes**

Friday, June 30, 2017
7:00 – 8:30 a.m. ET

Participants

Salvatore Alesci (Takeda), Neil Buckholtz (NIH/NIA), Rosa Canet-Avilés (FNIH), Lon Cardon (GSK), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Andrew Dahlem (Lilly), Mike Decker (AbbVie), Mikael Dolsten (Pfizer), Mark Erion (J&J), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Joseph Miletich (Merck), Gary Nabel (Sanofi), Dina Paltoo (NIH), Griffin Rodgers (NIH/NIDDK), Daniel Rotrosen (NIH/NIAID), Laurie Ryan (NIH/NIA), Susana Serrate-Sztejn (NIH/NIAMS), Phil Smith (NIH/NIDDK), Jim Sullivan (AbbVie), Marg Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH), Janet Woodcock (FDA)

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Mon, 4 Dec 2017 01:47:13 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Carter, Robert (NIH/NIAMS) [E]; 'Hodge, Martin' (Martin.Hodge@pfizer.com); Hoffmann, Steve (FNIH) [T]; Smith, Philip (NIH/NIDDK) [E]; thomas, Melissa; Kamphaus, Tania (FNIH) [T]; Vardanian, Lilit (FNIH) [T]; Ryan, Laurie (NIH/NIA) [E]; collier_david_andrew@lilly.com; Canet-Aviles, Rosa (FNIH) [T]; Sutherland, Margaret (NIH/NINDS) [E]; Fischer, Stephanie (SFischer@phrma.org); Melencio, Cheryl (FNIH) [T]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]
Subject: Materials for tomorrow AMP Extended Executive Committee pre-call
Attachments: AMP Extended EC 12-15-2017 DRAFT.pptx, 2017_06_30_AMP EEC teleconference final draft clean.docx, Copy of 15Dec2017_AMP EEC Teleconference.xlsx

Francis, all,
Please see the draft slide deck for tomorrow afternoon's pre-call and run-through of the AMP EEC call scheduled for 12/15. It includes the slidesets forwarded by the SC Co-chairs to date, minutes from the last EEC call in June, and list of respondents to date. I look forward to our conversation.
Thanks, David

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

Accelerating Medicines Partnership Extended Executive Committee Update #7

15 December 2017



NIH - 001



Accelerating Medicines Partnership Type 2 Diabetes

Phil Smith, NIDDK

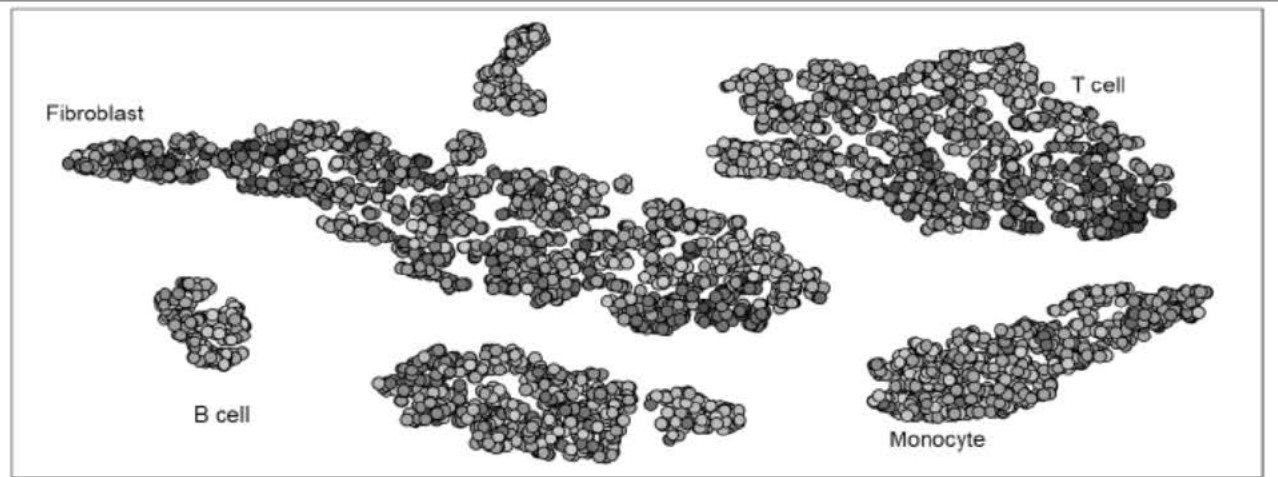
(b) (4)



NIH - 001



Accelerating Carter, NIAID



FNIH

Foundation for the
National Institutes of Health

NIH - 001996



Accelerating Medicines Partnership Alzheimer's Disease

Laurie Ryan, NIA



NIH - 002



(b) (4)

(b) (4)



NIH - 002032



b

- **Next Meeting:AMP Extended Executive Committee:
June 29**

Backup Slides

**Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Extended Executive Committee (EEC)
Teleconference Meeting Minutes**

Friday, June 30, 2017
7:00 – 8:30 a.m. ET

Participants

Salvatore Alesci (Takeda), Neil Buckholz (NIH/NIA), Rosa Canet-Avilés (FNIH), Lon Cardon (GSK), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Andrew Dahlem (Lilly), Mike Decker (AbbVie), Mikael Dolsten (Pfizer), Mark Erion (J&J), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Joseph Miletich (Merck), Gary Nabel (Sanofi), Dina Paltoo (NIH), Griffin Rodgers (NIH/NIDDK), Daniel Rotrosen (NIH/NIAID), Laurie Ryan (NIH/NIA), Susana Serrate-Sztejn (NIH/NIAMS), Phil Smith (NIH/NIDDK), Jim Sullivan (AbbVie), Marg Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH), Janet Woodcock (FDA)

(b) (4), (b) (5)

	A	B	C	D
1	December 15 AMP EEC			
2	Name	Attendance	Response	
3	Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None	
4	Alesci, Salvatore	Required Attendee	Tentative	
5	Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted	
6	Carrillo, Maria	Required Attendee	Accepted	
7	Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted	
8	Chin, Bill	Required Attendee	None	
9	Collier, David	Required Attendee	Accepted	
10	Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted	
11	Collins, Mary	Required Attendee	Accepted	
12	Dolsten, Mikael	Required Attendee	Accepted	
13	Eakin, Guy	Required Attendee	Accepted	
14	Ehlers, Michael	Required Attendee	Accepted	
15	Erion, Mark	Required Attendee	Accepted	
16	Fillit, Howard	Required Attendee	Declined	alternate: Andrew Koemeter-Cox
17	Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted	
18	Goldmuntz, Ellen (NIH/NIAID) [E]	Required Attendee	Accepted	
19	Hait, Bill	Required Attendee	Declined	
20	Hanrahan, Leslie	Required Attendee	Accepted	
21	Hendrix, James	Required Attendee	Accepted	
22	Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted	
23	Hodge, Martin	Required Attendee	Accepted	
24	Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted	
25	Kamphaus, Tania (FNIH) [T]	Required Attendee	Accepted	
26	Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted	
27	Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	None	
28	Lappin, Debra	Required Attendee	Declined	
29	Lepore, John	Required Attendee	Accepted	Cardon's replacement
30	Lifton, Richard	Required Attendee	Accepted	
31	List, James	Required Attendee	Accepted	
32	Lundberg, Jan	Required Attendee	Accepted	
33	Lynch, Thomas	Required Attendee	Accepted	
34	Marchiolo, Eryn	Required Attendee	Accepted	
35	McCulley, Jennifer	Required Attendee	Accepted	

	A	B	C	D
36	Menetski, Joseph	Required Attendee	Accepted	
37	Miletich, Joseph	Required Attendee	Accepted	
38	Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted	
39	Petanceska, Suzana (NIH/NIA) [E]	Required Attendee	Accepted	
40	Plump, Andrew	Required Attendee	Declined	sending alternate
41	Pragnell, Marlon	Required Attendee	Accepted	
42	Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted	
43	Rotrosen, Daniel (NIH/NIAID) [E]	Required Attendee	Accepted	
44	Ryan, Laurie (NIH/NIA) [E]	Required Attendee	None	
45	Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	Accepted	
46	Singh, Jyoti (NIH/OD) [E]	Required Attendee	Accepted	
47	Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted	
48	Stoffels, Paul	Required Attendee	Accepted	
49	Sullivan, Jim	Required Attendee	Tentative	
50	Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted	
51	Tabak, Lawrence (NIH/OD) [E]	Required Attendee	Accepted	
52	Tarrant, Teresa	Required Attendee	Accepted	
53	Terry, Sharon	Required Attendee	Accepted	
54	Thomas, Melissa	Required Attendee	Accepted	
55	Vallance, Patrick	Required Attendee	Declined	
56	Vardanian, Lilit	Required Attendee	Accepted	
57	Wholley, David (FNIH) [T]	Required Attendee	Accepted	
58	Woodcock, Janet (FDA/CDER)	Required Attendee	Accepted	
59	Zerhouni, Elias	Required Attendee	None	
60	Science writer			
61	Grabus, Sheri	Required Attendee	Accepted	

From: Wholley, David (FNIH) [T]
Sent: Wed, 29 Nov 2017 20:28:02 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]
Subject: Monday's AMP Extended EC Pre-Call

Francis:

We have a pre-call for the December 15 AMP Extended EC call on Monday December 4 from 2:30-3:30PM. So far it is just you and your team and my team. Since we are planning to run through the slide deck for the EEC, should we try to invite any of the co-chairs? We may not get all but would try for at least one from each of the 4 disease areas. Please let us know, thanks--David

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Dec 2017 15:38:53 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: note for Janet

Francis—draft note you requested below

Hi Janet –

I am writing to check in with you about the Opioids Partnership in-person meeting that FNIH is holding on December 12-13 next week at the Bethesda Marriott. We did our best to find dates that would work, but inevitably conflicts arise, and one of these apparently is a meeting that FDA is holding on packaging and disposal standards for opioids on December 11 and 12. My understanding is that this could have affect FDA attendance on the 12th in particular, involving schedules of Sharon Hertz and Ellen Fields in particular. I think reasonably senior FDA involvement would be important to send the right signal to the public and to our industry partners in particular. In that light, would you be willing to be there on the 12th? If not, can you help identify someone suitable to represent FDA at this critical juncture in our efforts?

Regards,
Francis

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

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(301) 594-6343

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Mon, 13 Nov 2017 03:03:13 +0000
To: Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Chin, Bill (Chin@phrma.org); Austin, Christopher (NIH/NCATS) [E]
Cc: Biarnes, Michael (FNIH) [T]
Subject: Had another conversation with Chris Flores on Friday afternoon

Dear All:

(b) (5)

(b) (5)

Thanks, David

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Fri, 15 Sep 2017 21:54:24 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: initial opioid partnership examples.docx
Attachments: initial opioid partnership examples.docx

Hi Francis:

(b) (5)



David

From: Wholley, David (FNIH) [T]
Sent: Fri, 22 Sep 2017 16:34:08 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: initial opioid partnership examples v2.docx
Attachments: initial opioid partnership examples v2.docx

Francis:

(b) (5)

(b) (5)

Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Sep 2017 15:17:32 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: Is it OK for Joe Menetski from NIH to call in to the Thursday morning call?

He's my deputy, 20 years' experience in pharma, expect him to help down the line. Strictly to listen in. I will ask Bill Chin but wanted to make sure OK with you first. Thanks, David

David Wholley
Director, Research Partnerships
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Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Fri, 6 Oct 2017 20:44:44 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
Subject: Just entered tunnel as you called on me

Should be about 3 mins
Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Thu, 6 Jul 2017 11:39:56 -0400
To: Collins, Francis (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]
Subject: PACT: (b) (4)

(b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Fri, 8 Sep 2017 16:10:41 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]
Subject: PACT (b) (4).

(b) (4)

Regards,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: (b) (4)
Sent: Friday, September 08, 2017 10:51 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; (b) (4)
Subject: Re: Checking in

(b) (4)

Sent from my iPhone

On Sep 8, 2017, at 4:19 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

EXTERNAL

(b) (4)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Fri, 3 Nov 2017 15:50:02 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: PACT EC

Hi Francis –

Back to PACT for a moment. Stacey Adam and I met with Jim Doroshow and his NCI team last night to start getting set for the face to face meeting we are holding on November 16 to finalize the detailed research plan for PACT (as we did with the AMP initiatives). Among the topics tackled was governance, and NCI is working on suggested representatives for the JSC.

(b) (4)

Thanks, David

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

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fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Sun, 20 Aug 2017 17:07:49 +0000
To: Collins, Francis (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; NIHDirectorMeetings; Melencio, Cheryl (FNIH) [T]
Subject: PACT Outreach Update -- Genentech is in
Attachments: PACT Outreach Update 082017.docx

Dear All:

I know we have a call currently scheduled for Thursday but thought I would give you all an update now on where things stand. Biggest news is that I **received an email from Edith Perez on Friday afternoon confirming that Genentech has found the funding for PACT and will join**; Stacey and I have a follow-up call scheduled with her Thursday noon:time to discuss the details. Summary, then:

YES – Abbvie, Boehringer-Ingelheim, BMS, Celgene, Genentech, Pfizer

(b) (4)


Status document (attached) has been updated to reflect all this.

Thanks,
David

From: Wholley, David (FNIH) [T]
Sent: Fri, 29 Sep 2017 13:04:02 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]
Subject: PACT partners

Jay,

Great to see you last night, as always. To follow up your question, the companies that have committed to PACT (b) (4) are AbbVie, BMS, Boehringer-Ingelheim, Celgene, Genentech, (b) (4) GSK, Janssen, and Pfizer. (b) (4)



Regards,
Francis

From: Wholley, David (FNIH) [T]
Sent: Tue, 3 Oct 2017 14:10:17 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Partnership to Accelerate Cancer Therapies
Attachments: Updated PACT Executive Summary 092617.docx

Dear (b) (4)

It has been a while since we spoke about this, but I wanted to ask you for a favor regarding another public-private partnership we have been developing: the Partnership to Accelerate Cancer Therapies (PACT). As you might recall, we've spent the last 15 months or so working with FNIH, FDA, and multiple pharmaceutical companies to plan a partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a \$160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (4) in industry funds to expand the number of novel markers, assays, and types of data that can be developed.

(b) (4)

The driving factor is that FNIH now has 8-9 companies pledged to support PACT, and that with encouragement from the White House we have committed to hold an announcement at the National Press Club downtown on October 12 (modeled on the announcements held for the Biomarkers Consortium and AMP).

(b) (4)

(b) (4)

I have attached a 2-page summary of PACT for reference, but please let me know if you have any additional questions.

Warm regards, Francis

<Updated PACT Executive Summary 092617.docx>

From: Wholley, David (FNIH) [T]
Sent: Wed, 27 Sep 2017 01:54:56 +0000
To: Bill Chin
Cc: Melencio, Cheryl (FNIH) [T]
Subject: PhRMA contribution to opioids partnership design

Hi Bill:

[REDACTED] (b) (6)

[REDACTED] (b) (4)

[REDACTED]

[REDACTED] I have some ideas about how this might work. Can we talk? Cheryl
Melencio can set up some time. Thanks,
David

Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Thu, 6 Jul 2017 18:42:04 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]; Canet-Aviles, Rosa (FNIH) [T]
Subject: Plan forward (b) (4) for AMP PD

Hi Francis –

Walter, Marg Sutherland, Todd Sherer, Rosa and I spoke this afternoon regarding Andy Conrad's request to add a wearable device project component to AMP PD. (b) (4)

(u) (+)

(b) (4) Considerations are:

- PPMI subjects will continue to be followed for the next 4-5 years, and while there is a push to make the protocol less intensive they will likely be at a stage of disease progression where testing a wearable device makes sense
- A similar idea has been discussed with PPMI leadership in the past but has never got beyond the talking stage, (b) (4)

(b) (4)

ACTION ITEMS:

1. Todd will talk with PPMI leadership and get their buy-in, identify any roadblocks, will let David W. know outcome (Todd is on vacation this week, but understands this is urgent).

2. (b) (4)

3.

4. (b) (4) to shop the proposal with the other AMP PD members, broker discussions with Pfizer etc

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Fri, 29 Sep 2017 12:53:16 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Melencio, Cheryl (FNIH) [T]
Subject: RE:

Yes, immediately.

(b) (4)

(b) (4)

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(301) 594-6343
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Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, September 29, 2017 5:25 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE:

Hi David,

Thanks for this draft. I will wait for the final news from Sanofi before sending.

(b) (4)

(b) (4)

(b) (4) He wanted to know what companies were definitely in. Can you draft a quick note that I could send him today?

FC

From: Wholley, David (FNIH) [T]
Sent: Thursday, September 28, 2017 8:48 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: FW:

Francis, Rebecca:

Below is the sample email, with attachment, that I showed you at our meeting today and that I drafted for Francis to send

(b) (4)

(b) (4)

(b) (4)

Please let me know if you need email addresses for any of these. Thanks, David

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Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Thursday, September 28, 2017 11:18 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW:

Dear Roger:

I wanted to give you an update on the Partnership for Accelerating Cancer Therapies (PACT). As you may recall NIH worked with FNIH, FDA, and 14 pharmaceutical companies (b) (4) earlier this year to plan a public-private partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a \$160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (4) to expand the number of novel markers, assays, and types of data that can be developed.

(b) (4)

(b) (4)

As a result, we now have X companies pledged to support PACT, and will be holding an announcement at the National Press Club here in Washington on October 12 with all of the participants, hosted by Secretary Price.

(b) (4)

(b) (4)

Do you might be able

to reconsider joining PACT given where things now stand? It would be great to know before the 12th so we can include you in the planning for the announcement.

(b) (4)

Regards,
Francis

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Learn more about the FNIH in our 2016 Annual Report: fnihi.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Mon, 4 Dec 2017 16:41:59 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: note to Janet Woodcock

Francis, you asked me to remind you to reach out to Janet today regarding FDA attendance at the face to face opioids partnership meeting on December 12-13, since we have not heard back definitively from Sharon Hertz about who will attend on those dates. As a heads up/reminder: 1) FDA has had a representative on 7 of the 9 Working Group calls we have had to date, which is pretty good 2) the main issue is December 12, when FDA has its own meeting on safe packaging for opioids 3) Sharon did say she'd find someone, it just can't be her or Ellen Fields or Doug Throckmorton, and has not said who yet. Therefore, I would probably soft shoe this a bit with Janet rather than complain we don't have anyone—you understand there is an important meeting that day, FDA challenged to find people to come on the 12th, perhaps Janet would like to attend herself since you will be there... etc.

Thanks, David

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Wed, 20 Dec 2017 00:37:50 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: Opioid PPP update for BMAC 12-19-17 draft for NIH
Attachments: Opioid PPP update for BMAC 12-19-17 draft for NIH.docx

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Dec 2017 00:08:27 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: Opioid PPP update for BMAC 12-19-17 integrated clean
Attachments: Opioid PPP update for BMAC 12-19-17 integrated clean.docx

Francis, please see the attached clean final draft of the opioids section of the update on FNIH partnerships requested by the BMAC. It has been reviewed by Larry, Nora, Walter, and Rebecca and I think captures the gist of our meeting and decision process to date. Please let me know any recommended changes as soon as possible so I can send to PhRMA. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Wed, 20 Dec 2017 21:10:15 +0000
To: Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: Opioid PPP update for BMAC 12-19-17 integrated
Attachments: Opioid PPP update for BMAC 12-19-17 integrated.docx

Thanks so much for integrating all the comments Rebecca. Attached are my answers to Larry's questions. I think his and Nora's suggested changes are good. David

From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Dec 2017 18:34:41 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: Opioids Design Phase F2F Dec 2017 Agenda - DRAFT 05Dec2017
Attachments: Opioids Design Phase F2F Dec 2017 Agenda - DRAFT 05Dec2017.docx

All – here is the latest version of the Agenda for next week’s face to face meeting, incorporating the changes we discussed last Thursday. We did just add 15 minutes for me to go over the agenda and introduce Francis at the very start. Please let us know if you have specific changes or comments—this is the version we will use with the co-chairs on our call Thursday unless we hear different. Thanks, David



Partnership to Address the Opioid Crisis Face-to-Face Meeting

Bethesda North Marriott Hotel – 5701 Marinelli Road, Rockville, MD 20852

Tuesday December 12th – 7:30 AM – 6:30 PM

Wednesday December 13th – 7:30 AM – 4:00 PM

Agenda

December 12th

WEBEX TO BE ADDED

Meeting number (access code):

Meeting password:

- | | |
|----------------------------|---|
| 7:30 am – 8:00 am | Registration and Breakfast |
| 8:00 am – 8:15 am | Agenda Overview, Meeting Logistics
<i>David Wholley (FNIH)</i> |
| 8:15 am – 8:30 am | Welcome and Introduction
<i>Francis Collins (NIH)</i> |
| 8:30 am – 8:45 am | Overview of Focus Area A
<i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i> |
| 8:45 am – 9:00 am | Overview of Focus Area B
<i>Walter Koroshetz (NINDS) [David Wholley (FNIH)]</i> |
| 9:00 am – 12:30 pm | Focus Area A: OUD Treatment and Overdose Prevention/Reversal
<i>Co-Chairs: Christopher Flores (J & J Consumer); Osman Cigeroglu (Pfizer)</i> |
| 9:00 am – 10:00 am | New Formulations/Combinations of Existing OUD Medications
<i>TBD</i> |
| 10:00 am – 10:15 am | Break |
| 10:15 am – 11:15 am | More Potent/Longer-lasting Antagonists to Reverse Overdose
<i>TBD</i> |
| 11:15 am – 12:15 pm | Alternative Endpoints for OUD Medications
<i>TBD</i> |



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Wednesday December 13th – 7:30 AM – 4:00 PM

Agenda

12:15 pm – 12:30 pm Focus Area A: Next Steps and Timelines for White Paper Development
TBD

12:30 pm – 1:00 pm Lunch

1:00 pm – 5:30 pm Focus Area B: Development of New Pain Medications Working Groups

1:00 pm – 3:00 pm Asset Repurposing Working Group
Co-Chairs – Chris Austin (NCATS), Chris Flores (Johnson & Johnson)

3:00 pm – 3:15 pm Break

3:15 pm – 5:15 pm Clinical Trials Network Working Group
Co-Chairs - Linda Porter (NINDS), Kenneth Verburg (Pfizer), Clinton Wright (NINDS)

5:15 pm – 5:30 pm Recap and Closing Remarks for Day 1
David Wholley (FNIH)

5:30 pm – 6:30 pm Networking Reception



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Tuesday December 12th – 7:30 AM – 6:30 PM

Wednesday December 13th – 7:30 AM – 4:00 PM

Agenda

December 13th

WEBEX TO BE ADDED

Meeting number (access code):

Meeting password:

- | | |
|----------------------------|---|
| 7:30 am – 8:00 am | Registration and Breakfast |
| 8:00 am – 8:15 am | Welcome and Introduction to Day 2
<i>David Wholley (FNIH)</i> |
| 8:15 pm – 12:30 pm | Focus Area B: Development of New Pain Medications Working Groups |
| 8:15 am – 10:15 am | Biomarkers Working Group
<i>Co-Chairs - Mark Mintun (Lilly), David Thomas (NIDA)</i> |
| 10:15 am – 10:30 am | Break |
| 10:30 am – 12:30 pm | Data Sharing Working Group
<i>Co-Chairs - John Dunlop (Amgen), Michael Oshinsky (NINDS)</i> |
| 12:30 pm – 1:15 pm | Lunch |
| 1:15 pm – 3:00 pm | Focus Area B: Refinement and Budgeting
<i>All Attendees</i> |
| 3:00 pm – 3:15 pm | Focus Area B: Next Steps and Timelines for White Paper Development
<i>David Wholley (FNIH)</i> |
| 3:15 pm – 4:00 pm | Closing Remarks |
| 3:15 pm – 3:30 pm | Summary of Focus Area A
<i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i> |



Partnership to Address the Opioid Crisis Face-to-Face Meeting

Bethesda North Marriott Hotel – 5701 Marinelli Road, Rockville, MD 20852

Tuesday December 12th – 7:30 AM – 6:30 PM

Wednesday December 13th – 7:30 AM – 4:00 PM

Agenda

3:30 pm – 3:45 pm Summary of Focus Area B
Walter Koroshetz (NINDS) [David Wholley (FNIH)]

3:45 pm – 4:00 pm Closing Remarks
Francis Collins (NIH)

4:00 pm Adjourn

DRAFT

From: Wholley, David (FNIH) [T]
Sent: Tue, 28 Nov 2017 21:08:27 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: Opioids Face-to-Face Meeting Invitation
Attachments: Partnership on Opioid and Pain - F2F Invitation List.xlsx

Dear All –

This is regarding the December 12-13 face to face. Can you please see below and let us know asap:

1. is the planned title for this meeting notice OK with you? I know we are still all thinking about a name for the partnership, but need to get the invitation out now
2. Is the summary description of the content appropriate? It needs to be short; wording is adapted from the latest document Rebecca sent to PhrMA. Note I have added an “asset repurposing” topic under pain
3. Can you please look over the attached attendee list and let us know any changes/additions? N.B. the guest list stands at 95 people currently.

We really need your feedback asap, preferably this evening (we can send out additional invitations a bit later if needed of course). Please copy Mike Biarnes on your replies.

Thanks, David

From: Biarnes, Michael (FNIH) [T]
Sent: Monday, November 27, 2017 1:42 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Opioids Face-to-Face Meeting Information

Hi David,

As discussed, we are working to send out the face-to-face meeting registration information to all members of Focus Area 1 and 2 today or tomorrow. In order to do so, a few items need to be finalized for the registration website:

- Title of the Partnership – *Suggested title for the site:* **Partnership on Opioids and Pain**
- Meeting Overview (*Suggested language below*)
- Invitation list (*compiled FA 1 and FA 2 list attached*)

Please let me know your thoughts so that we can finalize these items and get the registration information sent out to all of the working group members.

Thanks,
Mike

Draft Meeting Overview for the Registration Site:

"As part of a larger national effort to address the opioid crisis, NIH, the biopharmaceutical industry, and FDA are working in partnership to develop additional strategies to treat opioid addiction, prevent and reverse overdose, and accelerate the development of safe, non-addictive analgesics, and other effective strategies for pain management. Through consultations with partners to date, priority goals in two focus areas have been identified:

Focus Area A: Enhance the range of medication options to treat opioid use disorders and prevent/reverse overdoses.

1. Develop more potent or longer lasting opioid antagonists to reverse overdoses from fentanyl or its derivatives;
2. Develop more potent or longer lasting formulations and new medications to treat opioid use disorder.

Focus Area B: Develop new medications for pain relief, including safer, more effective, and non-addictive medications for pain.

3. Spur innovation in developing new pain medications through sharing of data and assets;
4. Establish new clinical trial networks with innovative study design to accelerate drug development in subpopulations of patients with different pain conditions;
5. Identify and validate biomarkers for pain.
6. Identify potential new uses for existing or abandoned medications in the treatment of pain.

The Foundation for the National Institutes of Health (FNIH) will convene stakeholders involved in designing the partnership to discuss the specific research plan steps needed to achieve each of these goals at an in-person meeting to be held on December 12-13, 2017, in Rockville, MD.

You have been specifically invited to attend this meeting on behalf of your organization. Information on meeting logistics and a link to respond to this invitation are below."

We've moved! Please find our new address below.

Michael Biarnes

Scientific Project Manager

Foundation for the National Institutes of Health

(301) 594-2612

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from [Charity Navigator](#).

From: Wholley, David (FNIH) [T]
Sent: Fri, 6 Oct 2017 22:24:08 +0000
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: Opioids partnership next steps

Francis, as requested:

(b) (5)

David Wholley
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*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Tue, 4 Jul 2017 22:07:12 -0400
To: Sutherland, Margaret (NIH/NINDS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]
Subject: Re: Any feedback you can give me from yesterday's meeting

As Walter has pointed out all the datasets in AMP PD are already collected. [REDACTED] (b) (4)

[REDACTED] (b) (4) David

Sent from my BlackBerry 10 smartphone.

From: Sutherland, Margaret (NIH/NINDS) [E]
Sent: Monday, July 3, 2017 5:52 PM
To: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]
Cc: Canet-Aviles, Rosa (FNIH) [T]
Subject: RE: Any feedback you can give me from yesterday's meeting

Hi Walter,
Here are some slides from MJFF on mobile technology. [REDACTED] (b) (4)

[REDACTED] (b) (4)
[REDACTED] (b) (4)
[REDACTED] (b) (4) From an NINDS perspective, we've been trying to learn from others as well. So far the enrollment on the mPower supplemental study for the NINDS Phase III trial has been slow. We would definitely need additional planning if mobile technology is to be part of AMP-PD, but with the adaptive design proposed, we could work that into Phase II of AMP-PD. Marg

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Monday, July 03, 2017 4:50 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Sutherland, Margaret (NIH/NINDS) [E] [REDACTED] (b) (6)>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: RE: Any feedback you can give me from yesterday's meeting

Thanks Francis. [REDACTED] (b) (4)

[REDACTED] (b) (4)

Wrinkle is that the projects as approved in phase 1 didn't have prospective data collection as part of AMP PD. Have to check on what MJ Fox is doing in terms of followup of PPMI—think more like 300 patients.

We are running a phase 3 clinical trial in PD and I encouraged the group to put in a supplement to add wearable technology to the assessments. I will check on where that is now.

Will get in touch with Bill Marks and get a path forward.

Walter

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, July 03, 2017 11:59 AM
To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Sutherland, Margaret (NIH/NINDS) [E] (b) (6)
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>
Subject: RE: Any feedback you can give me from yesterday's meeting

Hi all,

I just spent 30 minutes on the phone with Andy Conrad. He was apologetic about getting everyone worked up – because what he says he really wants to do is to make the study better, not pull out. And (b) (4)

Basically he is very enamored of the kind of data that can be derived from wearable sensors, and wants to see those included in the study design for the PPMI subjects. He told me about a recent study on multiple sclerosis (collab with Brigham) where accelerometers turned out to be a much better way to assess mobility than patient report or investigator measures with walking tests. That in turn allowed discrimination of patient subsets, leading to identification of molecular markers.

For the Netherlands PD study, 650 patients are using wearables to detect tremor, walking, and sleep (sounds like a combination of the spoon and a watch). He thinks the information is turning out to be quite valuable as a means of objective phenotyping. He wants to see the same done for those AMP-PD patients who are being followed prospectively.

(b) (4)

So this sounds like a win-win.

He'll talk with Bill Marks on Wednesday to explain this. He'd be glad to talk further with David or me about details.

So this sounds pretty good – but what am I missing?

FC

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Friday, June 30, 2017 6:06 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Sutherland, Margaret (NIH/NINDS) [E] (b) (6)

Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>

Subject: RE: Any feedback you can give me from yesterday's meeting

Very strange as they are in midst of launching Parkinson's study in Netherlands which dovetailed with PD AMP in terms of informatics infrastructure and also gives them access to tons more patients. If they also canceled the Netherlands study that would be a death knell.

Only other thing is that Sergay Brin is working through Milken foundation to "fact find" around best science in PD. They have meeting coming up in July. Could they be pulling back to do something on their own?? Or waiting? George Pavlov seems to be the person talking to Brin about PD.

Walter

From: Wholley, David (FNIH) [T]

Sent: Friday, June 30, 2017 9:10 AM

To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]

(b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)

Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>

Subject: Fw: Any feedback you can give me from yesterday's meeting

(b) (4)

(b) (4) I will reach out to Bill to ask for a call to ascertain more details, but any thoughts as to what we might do to mitigate the risk here? Can we point out synergies Verily may have working across NIH as part of the strategic fit? One hates to take a negative tack here, but are there indeed downside consequences for withdrawal I can point out to Bill? And is there any alternative--another in-kind technology partner we can feasibly approach?

Let me know if you'd like me to pull together a strategy call for next week sometime. It would be smart to involve Todd Sherer too, though I know he's left on his vacation as of early this week.

David

Sent from my BlackBerry 10 smartphone.

From: William Marks (b) (6)

Sent: Friday, June 30, 2017 8:46 AM

To: Wholley, David (FNIH) [T]

Cc: David Glazer

Subject: Re: Any feedback you can give me from yesterday's meeting

Hi, David.

(b) (4)

(b) (4)

(b) (4). David, I, and the team are regrouping later today to work further on this. We will keep you posted as we know more. I'm sorry for this less than happy news.

Bill

On Jun 30, 2017 3:38 AM, "Wholley, David (FNIH) [T]" <dwholley@fnihi.org> wrote:

Know it is early in CA but I am in a meeting with Francis Collins and Walter Koroshetz this morning and they will ask me about where things stand...thanks, David
Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Wed, 5 Jul 2017 09:08:21 -0400
To: Sutherland, Margaret (NIH/NINDS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]; Melencio, Cheryl (FNIH) [T]
Subject: RE: Any feedback you can give me from yesterday's meeting

By copy I will ask Cheryl to see if we can get something set up this week—you, Walter, me, Rosa, Todd. We may have to think outside the formal SC approval 'box' if we can... Francis you are of course welcome to join but want to be respectful of your schedule.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Sutherland, Margaret (NIH/NINDS) [E]
Sent: Wednesday, July 05, 2017 9:04 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koroshetz, Walter (NIH/NINDS) [E] <koroshetzw@ninds.nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: RE: Any feedback you can give me from yesterday's meeting

Hi David,
A phone call with Walter would be helpful, just so we are all on the same page. It seems we could create the possibility, but not a commitment for inclusion of MT, until after we've developed a plan and cost estimate for the SC. If there is interest from the SC, a discussion around inclusion of MT should be a significant focus for the next F2F. Marg

From: Wholley, David (FNIH) [T]
Sent: Tuesday, July 04, 2017 10:07 PM
To: Sutherland, Margaret (NIH/NINDS) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: Re: Any feedback you can give me from yesterday's meeting

As Walter has pointed out all the datasets in AMP PD are already collected. (b) (4)

(b) (4)

(b) (4) David

Sent from my BlackBerry 10 smartphone.

From: Sutherland, Margaret (NIH/NINDS) [E]

Sent: Monday, July 3, 2017 5:52 PM

To: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]

Cc: Canet-Aviles, Rosa (FNIH) [T]

Subject: RE: Any feedback you can give me from yesterday's meeting

Hi Walter,

Here are some slides from MJFF on mobile technology. MJFF has been strategically planning their next venture into mobile technology based on lessons learned from their Intel experience. To that end, MJFF has pulled together a Mobile Technology Advisory Council (MTAC) (slides give an overview) and are considering how to motivate PD participant buy-in. From an NINDS perspective, we've been trying to learn from others as well. So far the enrollment on the mPower supplemental study for the NINDS Phase III trial has been slow. We would definitely need additional planning if mobile technology is to be part of AMP-PD, but with the adaptive design proposed, we could work that into Phase II of AMP-PD. Marg

From: Koroshetz, Walter (NIH/NINDS) [E]

Sent: Monday, July 03, 2017 4:50 PM

To: Collins, Francis (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>;

Sutherland, Margaret (NIH/NINDS) [E] (b) (6)

Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>

Subject: RE: Any feedback you can give me from yesterday's meeting

Thanks Francis. Pfizer says they are also enamored of the wearable technology and plan similar study as Verily.

Wrinkle is that the projects as approved in phase 1 didn't have prospective data collection as part of AMP PD. Have to check on what MJ Fox is doing in terms of followup of PPMI—think more like 300 patients.

We are running a phase 3 clinical trial in PD and I encouraged the group to put in a supplement to add wearable technology to the assessments. I will check on where that is now.

Will get in touch with Bill Marks and get a path forward.

Walter

From: Collins, Francis (NIH/OD) [E]

Sent: Monday, July 03, 2017 11:59 AM

To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T]

<dwholley@fnih.org>; Sutherland, Margaret (NIH/NINDS) [E] (b) (6)

Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>

Subject: RE: Any feedback you can give me from yesterday's meeting

Hi all,

I just spent 30 minutes on the phone with Andy Conrad. He was apologetic about getting everyone worked up – because what he says he really wants to do is to make the study better, not pull out. (b) (4)

(b) (4)

Basically he is very enamored of the kind of data that can be derived from wearable sensors, and wants to see those included in the study design for the PPMI subjects. He told me about a recent study on multiple sclerosis (collab with Brigham) where accelerometers turned out to be a much better way to assess mobility than patient report or investigator measures with walking tests. That in turn allowed discrimination of patient subsets, leading to identification of molecular markers.

For the Netherlands PD study, 650 patients are using wearables to detect tremor, walking, and sleep (sounds like a combination of the spoon and a watch). He thinks the information is turning out to be quite valuable as a means of objective phenotyping. He wants to see the same done for those AMP-PD patients who are being followed prospectively.

(b) (4)

So this sounds like a win-win.

He'll talk with Bill Marks on Wednesday to explain this. He'd be glad to talk further with David or me about details.

So this sounds pretty good – but what am I missing?

FC

From: Koroshetz, Walter (NIH/NINDS) [E]

Sent: Friday, June 30, 2017 6:06 PM

To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Sutherland, Margaret (NIH/NINDS) [E] (b) (6)

Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>

Subject: RE: Any feedback you can give me from yesterday's meeting

Very strange as they are in midst of launching Parkinson's study in Netherlands which dovetailed with PD AMP in terms of informatics infrastructure and also gives them access to tons more patients. If they also canceled the Netherlands study that would be a death knell.

Only other thing is that Sergay Brin is working through Milken foundation to "fact find" around best science in PD. They have meeting coming up in July. Could they be pulling back to do something on their own?? Or waiting? George Pavlov seems to be the person talking to Brin about PD.

Walter

From: Wholley, David (FNIH) [T]
Sent: Friday, June 30, 2017 9:10 AM
To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Collins, Francis (NIH/OD) [E]
(b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>
Subject: Fw: Any feedback you can give me from yesterday's meeting

(b) (4)

(b) (4) will reach out to Bill to ask for a call to ascertain more details, but any thoughts as to what we might do to mitigate the risk here? Can we point out synergies Verily may have working across NIH as part of the strategic fit? One hates to take a negative tack here, but are there indeed downside consequences for withdrawal I can point out to Bill? And is there any alternative--another in-kind technology partner we can feasibly approach?

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David

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Know it is early in CA but I am in a meeting with Francis Collins and Walter Koroshetz this morning and they will ask me about where things stand...thanks, David
Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Thu, 2 Nov 2017 11:55:20 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: Re: biotech in PPP

We should discuss this in today's meeting.
Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Thursday, November 2, 2017 5:31 AM
To: Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]
Subject: biotech in PPP

Dear Rebecca,
For discussion—place of smaller biotechs in the PPP?

(b) (4)

Not sure where they would fit??.

Walter

Walter J. Koroshetz, M.D.
Director, National Institute of Neurological Disorders and Stroke

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 18:23:31 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: BMS is in

PS, I guess we never did hear back from Elias Z on PACT, did we?

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From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, October 11, 2017 1:51 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: BMS is in

I hear from Renate that Daniel Levine of BMS is being unresponsive to requests for quotes and representation at the press conference. Should I reach out to Tom Lynch?

FC

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Sent: Tuesday, October 10, 2017 10:38 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
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From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 10, 2017 10:33 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>

Cc: Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: RE: BMS is in

Just sent you two e-mails, that's what I have from conversations with Tom.

From: Wholley, David (FNIH) [T]
Sent: Tuesday, October 10, 2017 9:55 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: FW: BMS is in

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From: Collins, Francis (NIH/OD) [E]
Sent: Friday, July 28, 2017 7:41 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: BMS is in

(b) (4)

He was particularly glad to hear that FDA will be involved, as he thinks there is a great opportunity for precompetitive sharing of biomarker information.

FC

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 18:12:40 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: BMS is in

Not yet if you don't mind, he's trying. Was brought in on this last minute and is trying to coordinate across BMS. Let me try him again before you pull that trigger please.

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Subject: BMS is in

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To: Collins, Francis (NIH/OD) [E]
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Subject: BMS is in

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FC

From: Wholley, David (FNIH) [T]
Sent: Fri, 28 Jul 2017 12:17:52 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: Re: BMS is in

Great!!

Sent from my BlackBerry 10 smartphone.

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FC

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 19:11:19 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: BMS is in

Nor I from Joanne Lager. So it goes.

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I never heard from Elias.

Sent from my iPhone

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(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH)

[T] <sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshov, James (NIH/NCI)

[E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)

Subject: BMS is in

(b) (4)

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FC

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Oct 2017 14:23:32 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Re: can you call in at noon?

Sorry, Francis I am in a meeting with our Board until 3. I can follow up at that time or later.

David

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, October 16, 2017 10:14 AM
To: Wholley, David (FNIH) [T]
Subject: can you call in at noon?

I understand you might have a conflict with FNIH Board, but can you call in at noon for the opioid team meeting?

From: Wholley, David (FNIH) [T]
Sent: Tue, 7 Nov 2017 23:37:40 +0000
To: Chin, Bill; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: RE: Additional Thoughts

I think both of these require careful consideration. [REDACTED] (b) (5)

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, November 7, 2017 6:07 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E] [REDACTED] (b) (6)>
Subject: Additional Thoughts

All, I think our call was a good one. Two other thoughts. One, regarding communications, we might also consider the wisdom of a more public interim disclosure about our initial work in planning for the PPP. It would be a chance for the biopharmaceutical industry to indicate its support by virtue of the large representation of companies eager to help with the planning. Two, interactions with FDA. The more I think about the PPP, the more the criticality of early and continued conversations with the FDA becomes clear. [REDACTED] (b) (5)

[REDACTED] (b) (5) Bill

From: Wholley, David (FNIH) [T]
Sent: Tue, 12 Dec 2017 02:34:54 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]
Subject: Re: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Got it.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 11, 2017 9:33 PM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]
Subject: RE: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi David,

Wow, this is better but still seems overly detailed. With 66 slides I fear it will be hard to preserve much time for discussion in our 90 minute call.

Not including the title slides, I count 12 slides for T2D, 21 for RA/SLE, and 15 for AD. That makes me worry most about RA/SLE. I don't see how the team can present 21 data slides in 15 minutes without frustrating the listeners. Can you ask Bob Carter to consider this one more time, and potentially drop a few slides that are not essential? Slides 37 and 38 look like candidates for deletion to me.

Remembering a prior EEC where the introductory remarks from Mikael were elegant and inspiring, but went on WAY too long, shall I reach out to him to divide up that part, and emphasize that the introductory remarks should be very brief? In that regard, I'd recommend dropping slide 7 – it has a lot of details, and Lon and Patrick are no longer involved. Can be referred to verbally.

FC

From: Wholley, David (FNIH) [T]
Sent: Monday, December 11, 2017 4:25 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Singh, Jyoti (NIH/OD) [E]
(b) (6) Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi Francis – As requested, here is the second pass at the slides for the AMP EEC this Friday. We've done our best to work with the co-chairs to prune and improve the slides per your feedback on last week's pre-call. Let us know what you think, including where you think there are any additional opportunities for condensing this. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Tue, 12 Dec 2017 02:39:42 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Morgan, Emily (FNIH) [T]
Subject: Re: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

PS, yes please reach out to Mikael. Cheryl or Emily can you please make the deletions Francis has suggested and resend him the deck to use with Mikael? Thanks
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 11, 2017 9:33 PM
To: Wholley, David (FNIH) [T]
Cc: Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]
Subject: RE: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

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FC

From: Wholley, David (FNIH) [T]
Sent: Monday, December 11, 2017 4:25 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] (b) (6); Singh, Jyoti (NIH/OD) [E]
(b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi Francis – As requested, here is the second pass at the slides for the AMP EEC this Friday. We've done our best to work with the co-chairs to prune and improve the slides per your feedback on last week's pre-call. Let us know what you think, including where you think there are any additional opportunities for condensing this. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Tue, 3 Oct 2017 13:00:16 +0000
To: Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]
Subject: Re: An idea: getting drug companies to share negative data

(b) (5)

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 3, 2017 6:57 AM
To: Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David (FNIH) [T]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]
Subject: Fwd: An idea: getting drug companies to share negative data

See below and attached.

(b) (5)

Sent from my iPhone

Begin forwarded message:

From: "Ed Boyden, esb@media.mit.edu" (b) (6)
Date: October 3, 2017 at 5:43:51 AM EDT
To: "Volkow, Nora (NIH/NIDA) [E]" (b) (6)
Cc: Katharina Sophia Volz <volz@occamzrazor.com>, kaya c tilev <kaya@occamzrazor.com>, "Collins, Francis (NIH/OD) [E]" (b) (6), Bertha Madras (b) (6)
Subject: Re: An idea: getting drug companies to share negative data
Reply-To: (b) (6)

Dear Francis, Nora, Bertha,

Building from your great feedback -- we have sketched out a brief article -- which we may extend, and submit for publication, but wanted your early reactions -- about the open questions relating to creating a market for negative data in biomedicine. The goal was to understand the conditions that must be fulfilled, in order for this idea to have a feasible economic trajectory. Obviously there are a lot of uncertainties relating to how such an idea would be deployed, and feedback from potential participants in the market could be useful (or maybe the right next step would be just "giving it a try").

We would love to hear your thoughts, if you might have a moment!

Best,
Ed

On Wed, Jul 19, 2017 at 2:46 PM, Ed Boyden, esb@media.mit.edu

(b) (6) wrote:

Thanks so much for the helpful thoughts, Nora, Francis, and Bertha!
We will work on the idea further, then, and be in touch as thoughts mature.

Best,
Ed

On Fri, Jul 14, 2017 at 3:09 PM, Volkow, Nora (NIH/NIDA) [E]

(b) (6) wrote:

Dear Ed: I like the concept because I agree that this would incentivize sharing of data (perhaps even compounds) that otherwise would remain in "drug and data cemeteries". Of course, the trick will be on the details of how to make it work. nora

On 7/13/17, 9:30 AM, "Ed Boyden, esb@media.mit.edu" (b) (6) wrote:

Dear Francis, Bertha, Nora,

There's clearly a lot of inertia related to the problem of getting drug companies to open up more, especially regarding sharing negative data. A few of us (cc'ing Katharina and Kaya, at the new startup company Razor, Inc., which I advise) have been thinking about a new idea: to create a *market* for negative data. What if, say, we created a secure environment for the storage of the data, and then a team (under nondisclosure) could mine the data for interesting clues? Then, new drugs could be invented taking advantage of the new information. Suppose, say, 60% of the profits would go to the company developing the new drug, but the other 40% would be split between the companies whose negative data contributed. It would be split up in a fair way that would take into account the cost to produce this data (in vitro, in vivo for preclinical or Phase I, II or III for clinical trials). This would incentivize sharing. Key to this working would be a way to track the flow of information to assign credit properly -- something the Razor team has started to think about, at a software level. What do you think? Hope all is well!

Best,
Ed

--

Ed Boyden, Ph. D.

Leader, Synthetic Neurobiology Group

Associate Professor, MIT Media Lab and McGovern Institute,

Departments of Biological Engineering and Brain and Cognitive Sciences

Co-Director, MIT Center for Neurobiological Engineering

Massachusetts Institute of Technology

Building E15: E15-421, 20 Ames St., Cambridge, MA 02139 (mailing address)
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email - esb@media.mit.edu
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cell - (b) (6)
fax - (617) 253-6285
Google Hangout - (b) (6)
skype - eboyden3
web - <http://syntheticneurobiology.org>
twitter - <http://twitter.com/eboyden3>

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Ed Boyden, Ph. D.
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skype - eboyden3
web - <http://syntheticneurobiology.org>
twitter - <http://twitter.com/eboyden3>

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fax - (617) 253-6285
Google Hangout - (b) (6)
skype - eboyden3

web - <http://syntheticneurobiology.org>
twitter - <http://twitter.com/eboyden3>

From: Wholley, David (FNIH) [T]
Sent: Thu, 16 Nov 2017 13:30:47 +0000
To: Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: Another Time Sensitive Request: Opioid Partnership Co-Chair

He's been pretty involved in the pain discussions>

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, November 15, 2017 6:44 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E]
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Subject: FW: Another Time Sensitive Request: Opioid Partnership Co-Chair

Well, that one didn't go through.

From: Pamela J Edmonds [mailto:edmonds_pamela_j@lilly.com] **On Behalf Of** Jan Lundberg
Sent: Wednesday, November 15, 2017 5:26 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)>
Cc: Daniel Skovronsky <skovronsky_daniel@lilly.com>; Timothy Garnett <garnett_tim@lilly.com>; (b) (6)
(b) (6) David A Ricks <ricks_david@lilly.com>; Andrew H Ahn <andyahn@lilly.com>
Subject: RE: Another Time Sensitive Request: Opioid Partnership Co-Chair

Dear Francis,

Thank you for your recent email concerning (b) (4) availability to consult more extensively on the work group developing new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose. As you well know, (b) (4) is already co-chairing one half of the group that is looking at developments in non-opioid pain medications. This really reflects both (b) (4) and Lilly's current expertise. Andy Ahn from Lilly is also a member of the opioid work group to learn more about the difference between addictive and non-addictive pain mechanisms. We believe that if the work to develop new formulations and combinations of medications to treat opioid use disorders, and prevent overdose is to be truly effective, it really needs to be led by, and primarily leverage experts from biopharma companies who are active in the opioid field.

In addition, this work and (b) (4) current responsibilities here at Lilly would really preclude him from being able to commit any further time to the efforts in the short-term.

Best,

Jan

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, November 09, 2017 6:44 PM
To: Jan Lundberg <lundberg_jan@lilly.com>
Cc: Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: [EXTERNAL] Another Time Sensitive Request: Opioid Partnership Co-Chair

Dear Jan,

Thank you again for agreeing for (b) (4) to serve in this role.

As we continue our planning process for this partnership to bring about early successes in the opioid crisis, we have thought more about the potential value of having (b) (4) provide advice toward our first and more near-term goal: to develop new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose.

The additional time commitment for (b) (4) would include 2-3 teleconferences and attendance at the one in-person meeting, now planned for early December, that will address both the pain and addiction focus areas. In this effort, (b) (4) would work with Nora Volkow, the Director of the National Institute on Drug Abuse and her staff in the initial design phase for this focus area of the partnership.

Would you be willing to consider (b) (4) in this additional role? As always, I would be happy to discuss further or answer any questions you may have. I have copied Nora Volkow and Jack Stein of NIDA, who are helping lead this effort as well. Given our very abbreviated time table, I would be grateful to hear back from you on this by the middle of next week.

Warm regards,
Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, November 1, 2017 6:12 PM
To: Jan Lundberg <lundberg_jan@lilly.com>
Cc: (b) (6) Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); David A Ricks <ricks_david@lilly.com>
Subject: RE: [EXTERNAL] Time Sensitive Request: Opioid Partnership Co-Chair

That's great news, thanks!

Best, Francis

From: Jan Lundberg [mailto:lundberg_jan@lilly.com]

Sent: Wednesday, November 01, 2017 1:48 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: (b) (6) Koroshetz, Walter (NIH/NINDS) [E]

(b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); David A Ricks <ricks_david@lilly.com>

Subject: Re: [EXTERNAL] Time Sensitive Request: Opioid Partnership Co-Chair

Francis, we are very positive to (b) (4) leading topic 2 :non addictive pain therapies and he has also agreed. So please move on in this highly needed area of new better and safer medicines!

Best

Jan

Sent from my iPhone

On Oct 31, 2017, at 2:16 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Jan,

I am writing to you today about a new partnership effort, this one with FDA and as many as 30 potential company partners to address the national opioid abuse crisis. We have made considerable progress in defining an initial research agenda, and are at point of convening our partners to refine it into a final design over the next several months. I am writing to ask if (b) (4) could play a key leadership role in this effort.

As a result of our discussions to date—in which (b) (4) participated--we've selected two focus areas for the partnership:

1. Develop new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose
2. Develop new non-addictive pain therapies.

The next steps involve convening a Working Group of experts from NIH, the interested industry partners, and several key academic opinion leaders to agree on the research plan. We are looking to select one industry scientist and one NIH representative to co-chair each of the Working Groups. Both Walter Koroshetz and Linda Porter of NIH's National Institute of Neurological Disorders and Stroke enthusiastically recommended Mark to serve as the industry co-chair for focus area #2 in developing new pain therapies.

The time commitment for (b) (4) would entail 3-4 teleconferences (a couple of hours each) and at least one in-person, full-day meeting in late November or early December, with the key deliverable being a white paper describing the consensus of the group on a common mission and a high-level plan. Given

the magnitude of the crisis, and the strong interest of the current Administration and the Congress, we'd like to solidify a plan and gather the necessary funding commitments by the end of this year, with a view to funding and launching an effort in early 2018. We are engaging the Foundation for the NIH to manage this effort, and (b) (4) would be fully staffed by FNIH to make this successful.

Would you be willing to consider (b) (4) in this role? I will be happy to answer any questions you may have or discuss further, and am copying David Wholley at FNIH, who is helping lead this effort, as well. I hope I will hear back from you on this by the middle of next week.

Warm regards,
Francis

From: Wholley, David (FNIH) [T]
Sent: Wed, 5 Jul 2017 08:48:37 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Any feedback you can give me from yesterday's meeting

Sorry for the late response Francis—I was traveling with family and did not have my laptop with me.

(b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, July 03, 2017 11:03 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Any feedback you can give me from yesterday's meeting

I'm speaking with Andy Conrad in 15 minutes.

(b) (4)

FC

From: Wholley, David (FNIH) [T]
Sent: Friday, June 30, 2017 5:19 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Any feedback you can give me from yesterday's meeting

Hi, Francis:

Thanks for responding so late on holiday Friday. Unfortunately I do not have a phone number or email for Andy, and my search (Google of course...) of the web has turned up nothing. Judging by the email addresses I have seen of other Verily employees, you might try (b) (6) or (b) (6). Otherwise my only other recourse would be Cheryl who is out of the office until Wednesday at this point.

As for Verily's role: as you know, AMP PD is designed to identify and develop biomarkers that can be used to support design of PD clinical trials, taking advantage of already existing clinically phenotyped, longitudinal, genetically characterized PD cohorts with linked longitudinal biobanks (*PPMI, PDBP, Harvard Biomarkers Study, PARS, and others*). Proposed assays include deep molecular characterization, neuroimaging, multimodal imaging, and profiling of PD patients. The proposal includes a plan for open

data access and sharing to dissect new targets, disease subtypes, and markers that track and predict progression. All the results will be made broadly available through an AMP-PD Knowledge Platform. Verily has proposed to provide in-kind software development and services to support data management, analytical pipelines, and visualization tools. They were to have included cloud-based hosting services for the Knowledge Platform as part of this, but that element is actually not nearly as important as the analytical software development piece—which they could potentially reuse across any number of similar projects. Although it is rather dated (still includes Proposal 1 for example) the attached Technical Plan we sent them over the winter really is not too different from the current requirements Verily would be addressing from an informatics point of view.

On another subject, Stacey Adam and I spoke with Edith Perez, the CMO of Genentech, about a half hour ago regarding PACT. (b) (4)

(b) (4)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnihi.org

Learn more about the FNIH in our 2016 Annual Report: fnihi.org/AnnualReport.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, June 30, 2017 3:02 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Subject: RE: Any feedback you can give me from yesterday's meeting

Will do.

Might you have a phone number or e-mail? I don't seem to have readily available.

I need to understand better what Verily's actual role was supposed to be. Can you help me with that?

FC

From: Wholley, David (FNIH) [T]
Sent: Friday, June 30, 2017 2:08 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: Any feedback you can give me from yesterday's meeting

I just spoke to Tom.

(b) (4)

(b) (4)

(b) (4) That is, if rational arguments work

at all. Tom asked to be kept abreast of outcome on this, fyi. Thanks as always. David
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]

Sent: Friday, June 30, 2017 10:58 AM

To: Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]

Cc: Canet-Aviles, Rosa (FNIH) [T]

Subject: RE: Any feedback you can give me from yesterday's meeting

Oy. If it would help for me to reach out to Andy Conrad, I will.

FC

From: Wholley, David (FNIH) [T]

Sent: Friday, June 30, 2017 9:10 AM

To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]

(b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)

Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>

Subject: Fw: Any feedback you can give me from yesterday's meeting

(b) (4)

(b) (4) I will reach out to Bill to ask for a call to ascertain more details, but any thoughts as to what we might do to mitigate the risk here? Can we point out synergies Verily may have working across NIH as part of the strategic fit? One hates to take a negative tack here, but are there indeed downside consequences for withdrawal I can point out to Bill? And is there any alternative--another in-kind technology partner we can feasibly approach?

Let me know if you'd like me to pull together a strategy call for next week sometime. It would be smart to involve Todd Sherer too, though I know he's left on his vacation as of early this week.

David

Sent from my BlackBerry 10 smartphone.

From: William Marks (b) (6)

Sent: Friday, June 30, 2017 8:46 AM

To: Wholley, David (FNIH) [T]

Cc: David Glazer

Subject: Re: Any feedback you can give me from yesterday's meeting

Hi, David.

(b) (4)

(b) (4)

I know this news and lack of certainly puts you in a precarious situation. David, I, and the team are regrouping later today to work further on this. We will keep you posted as we know more. I'm sorry for this less than happy news.

Bill

On Jun 30, 2017 3:38 AM, "Wholley, David (FNIH) [T]" <dwholley@fnihi.org> wrote:

Know it is early in CA but I am in a meeting with Francis Collins and Walter Koroshetz this morning and they will ask me about where things stand...thanks, David
Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Sun, 10 Sep 2017 18:53:13 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]
Cc: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Agree. The key will be pre-agreement on the nature of the questions we will be asking the shared data to answer.

Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Saturday, September 9, 2017 8:30 PM
To: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]
Cc: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Sounds good. Recall that Ken Verburg spoke most about this topic. He acknowledged that it was counter to their culture to help another company from going down a rabbit hole but.... In face of a crisis thought maybe the lawyers might be sidelined???

w

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, September 09, 2017 2:40 PM
To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T]
(b) (6)
Cc: Volkow, Nora (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Just a heads up from my conversation Friday with Bill Chin – industry is a bit sensitive about the data sharing issue, at least when it is expressed broadly. They think they’ve actually been doing a better job than many academics. Let’s make it clear that the kind of data sharing we are talking about including in the PPP is rather specific: availability of preclinical or clinical trial data on unapproved compounds (especially those that have failed for efficacy or toxicity, and are no longer being pursued), which would normally not be made available. Let’s also be clear that NIH’s willingness to serve as honest broker doesn’t mean we are finger-wagging at industry.

FC

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Friday, September 08, 2017 1:44 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Volkow, Nora (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]
(b) (6); Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence
(NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda
(NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Data sharing needs to be part of it.

Walter J Koroshetz MD
Director, National Institute of Neurological Disorders and Stroke/NIH

Sent from my iPhone

On Sep 8, 2017, at 9:23 AM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

No, roundtable is the appropriate word, but it is now the only thing suggested. And if talk is all we suggest, that is all we are likely to get.

Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Friday, September 8, 2017 8:34 AM
To: Wholley, David (FNIH) [T]
Cc: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Ken Verburg did propose that the company folks would sit around the table and share lessons learned. the somewhat radical idea is that they could prevent companies from wasting time and money doing things that already failed for another. Data sharing of company data for data mining was next piece which led to the point that they would exclude the parasites- ie. those that take but don't put up their data.

Sitting around the table was the phrase , is "roundtable" the wrong word???

Walter J Koroshetz MD
Director, National Institute of Neurological Disorders and Stroke/NIH

Sent from my iPhone

On Sep 8, 2017, at 8:02 AM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Walter, thanks for adding specificity to some of these. I don't recall however that the proposed data sharing involved just a roundtable--which sounds like a discussion--but an actual database.

Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Thursday, September 7, 2017 9:08 PM
To: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wholley, David (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Thanks so much Rebecca. Nice job as usual. Please find suggestions for edits.
Best wishes,

Walter

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Thursday, September 07, 2017 4:20 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6)>; Collins, Francis (NIH/OD) [E] (b) (6)>; Tabak, Lawrence (NIH/OD) [E] (b) (6)>; Koroshetz, Walter (NIH/NINDS) [E] (b) (6)>; Stein, Jack (NIH/NIDA) [E] (b) (6)>; Porter, Linda (NIH/NINDS) [E] (b) (6)>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6)>
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Rebecca this is a very good summary. The only other item that is not listed but that was brought up by the participants was that REGULATORY PATHWAYS and how PPP could be used for FDA to help pharma. Though how one would construct such a facilitatory role in a PPP is not completely clear. nora

From: "Baker, Rebecca (NIH/OD) [E]" (b) (6)>
Date: Thursday, September 7, 2017 at 1:48 PM
To: Francis Collins <(b) (6)>, "Tabak, Lawrence (NIH/OD) [E]" (b) (6)>, Nora Volkow (b) (6)>, Walter Koroshetz (b) (6)>, Jack Stein (b) (6)>, "Porter, Linda (NIH/NINDS) [E]" (b) (6)>, "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Wolinetz, Carrie (NIH/OD) [E]" (b) (6)>
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)>
Subject: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Good afternoon,

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We are hoping to send this out when memories are fresh, and in time to inform the 9/11 PhRMA meeting. Thank you in advance for your quick turnaround suggested edits.

Best,

Rebecca

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, September 6, 2017 4:58 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>;
Wolinetz, Carrie (NIH/OD) [E] (b) (6)>
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E]
(b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke,
Hilda (NIH/NIDA) [E] <(b) (6)>; Walker, Paula (NIH/NINDS) [E] (b) (6)
Hardesty, Rebecca (NIH/OD) [C] (b) (6); Melencio, Cheryl (FNIH) [T]
<cmelencio@fnihi.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6); Wood, Gretchen
(NIH/OD) [E] (b) (6)
Subject: Meeting materials: tomorrow's 9- 7- 2017 opioid and pain partnership planning meeting

Good afternoon,

Please find attached materials for tomorrow's teleconference in preparation for the Sept 11 Pain and Opioid Initiative Planning Meeting with PhRMA and industry colleagues.

The NIH team will gather at 7AM in Building 1, Room 116 for the presentation and discussion. I will bring hard copies of all materials, and the slides will also be shared via Webex.

Please let me know if you have any questions or concerns.

Thank you and see you tomorrow,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Thu, 7 Sep 2017 21:23:32 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Tabak, Lawrence (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning mkeeting: industry interest matrix

Looks good.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Thursday, September 7, 2017 5:07 PM
To: Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Tabak, Lawrence (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wholley, David (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Thanks again.

Attached is a clean revised table. Please note the changes described below:

A revised introduction including a 4th element in the priority score suggested by Bill Chin and description of the forthcoming process suggested by FC.

A third program area was added directed at regulatory pathways. I didn't think that this belonged in either program area #1 or #2, but please feel free to disagree.

Kellie of PhRMA is assembling the email distribution list for FC and Bill Chin to send this out together, as we did for the initial meeting invitations.

Please let me know if you have any questions or concerns.

Thank you,

Rebecca

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 07, 2017 4:27 PM
To: Volkow, Nora (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] <(b) (6)>
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Good idea to put that in, I'm sure it will be rated highly.

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Thursday, September 07, 2017 4:20 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E]
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnih.org>;
Wolinetz, Carrie (NIH/OD) [E] (b) (6)>
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6)>
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest
matrix

Rebecca this is a very good summary. The only other item that is not listed but that was brought up by the participants was that REGULATORY PATHWAYS and how PPP could be used for FDA to help pharma. Though how one would construct such a facilitatory role in a PPP is not completely clear. nora

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Date: Thursday, September 7, 2017 at 1:48 PM
To: Francis Collins (b) (6), "Tabak, Lawrence (NIH/OD) [E]"
(b) (6), Nora Volkow (b) (6), Walter Koroshetz
(b) (6), Jack Stein (b) (6), "Porter, Linda (NIH/NINDS) [E]"
(b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Wolinetz, Carrie
(NIH/OD) [E]" (b) (6)>
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)>
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Best,

Rebecca

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, September 6, 2017 4:58 PM

To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke, Hilda (NIH/NIDA) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6); Hardesty, Rebecca (NIH/OD) [C] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6)
Subject: Meeting materials: tomorrow's 9- 7- 2017 opioid and pain partnership planning meeting

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The NIH team will gather at 7AM in Building 1, Room 116 for the presentation and discussion.
I will bring hard copies of all materials, and the slides will also be shared via Webex.

Please let me know if you have any questions or concerns.

Thank you and see you tomorrow,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Wed, 19 Jul 2017 14:25:36 -0400
To: Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]
Subject: Re: Follow-Up on AMP PD

Don't know for sure but assume that it is still there in the background and we will certainly bring it up. Given that we are just at the beginning with wearables and that there is no guarantee we'd not encounter obstacles there I would not be in a hurry to re-establish a conditional link between the two.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, July 18, 2017 8:47 PM
To: Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]
Cc: Canet-Aviles, Rosa (FNIH) [T]
Subject: RE: Follow-Up on AMP PD

Very encouraging. (b) (4)

From: Wholley, David (FNIH) [T]
Sent: Tuesday, July 18, 2017 8:45 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)
Cc: Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: FW: Follow-Up on AMP PD

All:

Please see below. This is the best possible outcome I could have imagined. (b) (4)

(b) (6) As Marg has pointed out the cloud computing services are really not all that significant in the scheme of things. I have asked Bill if Marg Sutherland can join the follow-up call, which Emily Morgan from our staff will coordinate. Onward.

Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: William Marks (b) (6)
Sent: Monday, July 17, 2017 10:10 PM
To: Wholley, David (FNIH) [T] <dwholley@fni.h.org>
Cc: David Glazer (b) (6); Ritu Kapur (b) (6); Thomas Snyder (b) (6)
Subject: Follow-Up on AMP PD

Dear David,

I'm writing to share some positive news with you.

We at Verily have had additional discussions, and out of these talks have emerged the following:

(b) (4)

We'd like to arrange a phone call to discuss further. Might any of these dates/times work for you and your colleagues:

7/20: 11am-12noon Eastern Time

7/21: 11am-12noon or 5-6pm Eastern Time

Thanks--we're looking forward to discussing further.

Bill (for the Verily Team)

William J. Marks, Jr., MD, MS-HCM | 415-736-7580 | (b) (6)

Verily

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Sep 2017 13:19:50 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Morgan, Emily (FNIH) [T]; Melencio, Cheryl (FNIH) [T]
Subject: Re: FOR YOUR REVIEW: letter from FC and PhRMA to potential partners re PPP

Yes Francis I can speak then. Cheryl is out of office so Emily Morgan is handling my calendar today.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 21, 2017 5:27 AM
To: Wholley, David (FNIH) [T]
Subject: FW: FOR YOUR REVIEW: letter from FC and PhRMA to potential partners re PPP

Hi David,

Your experienced eye is really needed here. Any chance you could be free around 12:30 PM for a phone call with me and Rebecca?

Francis

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, September 20, 2017 11:41 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) Volkow, Nora (NIH/NIDA) [E]
(b) (6) Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Stein, Jack (NIH/NIDA) [E] (b) (6) Porter, Linda (NIH/NINDS) [E] (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Subject: FOR YOUR REVIEW: letter from FC and PhRMA to potential partners re PPP

Dear all,

To maintain the momentum from Monday's meeting in New Jersey, Francis and Steve Ubl of PhRMA, are writing a note to send to representatives from all the companies that have contributed to the partnership planning to date, asking them to join in the next step of defining the PPPs. A draft note is attached for your consideration.

A few issues to consider before we send out the request. Not all of the partnership areas will follow the same path. Some will be AMP-like in design, whereas for others we'll be asking the companies to provide materials, in-kind support, and expertise toward a shared goal, but not co-funding and the shared governance structure that goes with it. However, all the components will still need shared involvement by industry partners.

One strategy to manage these differences might be to divide early on the development and governance structures of projects #1 and #2. If we pursue this approach, Project #1 will need some sort of shared

coordination process with substantive high level involvement by relevant companies. What might this structure look like, and would a neutral party such as FNIH be needed to facilitate?

Could we envision a joint NIH-FDA-industry steering committee for project #1 convened and managed by NIDA? Project #2 could have a jointly funded structure with FNIH management. We might also consider an overarching structure or other way to ensure the two projects stay in touch despite the different approaches.

Lastly, so as not to surprise our partners, the letter will request both a representative and a monetary contribution for the planning process. Does this group have any concerns or sensitivities with that request coming now?

We are hoping to find a time soon to discuss these next steps in person or on the phone. However since folks are out for the holiday, and we'd like to send this note out this week, we'd appreciate your thoughts via email until then.

Thank you,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Sep 2017 21:50:17 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: FOR YOUR REVIEW: letter from FC and PhRMA to potential partners re PPP
Attachments: OpioidPartnershipInvite fsc DWrev9-22.docx

Hi Rebecca,

Attached are my additional suggested changes on your strong start. Sorry, did not see Walter's note till just now, hopefully not a problem to integrate the two.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

fnih.org

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From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Thursday, September 21, 2017 4:00 PM
To: Baker, Rebecca (NIH/OD) [E]; (b) (6); Collins, Francis (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E]; (b) (6); Wholley, David (FNIH) [T]
<dwholley@fnih.org>; Stein, Jack (NIH/NIDA) [E]; (b) (6); Porter, Linda (NIH/NINDS) [E]
(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E]; (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6)
Subject: RE: FOR YOUR REVIEW: letter from FC and PhRMA to potential partners re PPP

Thanks Rebecca—minor details but if could update the pain section to include the red"
Project #2: Accelerate Development of New Non-Addictive Pain Therapies:

(b) (5)



Walter

From: Baker, Rebecca (NIH/OD) [E]
Sent: Thursday, September 21, 2017 2:31 PM
To: Collins, Francis (NIH/OD) [E]; (b) (6); Volkow, Nora (NIH/NIDA) [E]
(b) (6); Koroshetz, Walter (NIH/NINDS) [E]; (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Stein, Jack (NIH/NIDA) [E]; (b) (6); Porter, Linda

(NIH/NINDS) [E] (b) (6)

Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)

Subject: RE: FOR YOUR REVIEW: letter from FC and PhRMA to potential partners re PPP

Please find attached a revised version of the letter that takes into account feedback from David.

Thanks in advance for your thoughts,

Rebecca

From: Baker, Rebecca (NIH/OD) [E]

Sent: Wednesday, September 20, 2017 11:41 PM

To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)

Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)

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(b) (5)

(b) (5)

(b) (5) We might also consider an overarching structure or other way to ensure the two projects stay in touch despite the different approaches.

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Thank you,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Tue, 12 Sep 2017 15:24:19 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Invite Confirmations for September 18th as of today

Thanks. I thought it went well overall.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Collins, Francis (NIH/OD) [E]
Sent: Monday, September 11, 2017 9:06 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Invite Confirmations for September 18th as of today

FYI

From: Chin, Bill [<mailto:Chin@phrma.org>]
Sent: Monday, September 11, 2017 8:50 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)
Subject: Re: Invite Confirmations for September 18th as of today

As noted below, the Executive Session resulted in consensus view to move forward with focus on the higher prioritized projects. There is a desire to focus on shorter timeframe deliverables and areas that are more likely precompetitive. I appreciate Rebecca [the amazing Rebecca] taking a shot at this; we will as well. Tomorrow we will work to “entice” more CEOs to participate next week. I have re-arranged my travel so that I should be able to attend as well. Let me know when Amy has settled on an agenda with hopes that she’ll leave some time for PhRMA. Thanks again to you and your team. Bill

On Sep 11, 2017, at 8:34 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi Bill,

We agree that the meeting went really well today (though of course we don't know about the Exec session). Rebecca has volunteered to put together the first draft of a 1 – 2 pager pre-read. Then the rest of us can do a quick review.

Best, Francis

From: Chin, Bill [<mailto:Chin@phrma.org>]
Sent: Monday, September 11, 2017 6:41 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6)
Subject: RE: Invite Confirmations for September 18th as of today

Thanks, Francis, Nora and Walter. The list is getting better. Let me check with Pfizer before you approach. Also, I thought that we had a good meeting. In Executive Session, we all agreed to move forward with next steps. However, the group note that it would be useful to have a 1—2 pager pre-read about our plans to date and those going forward for the CEO meeting. I can take a shot at it for your review, comments and edits in the next 24 hours, or vice versa—your choice. Then we could send it back to BMAC for their review prior to forwarding to the CEOs, perhaps by early Friday. Bill Again, many thanks to Carrie and Rebecca as well. BTW, Dolly Moorhead confirmed that Reed Cordish will be attending the 9/18 meeting.

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Monday, September 11, 2017 5:29 PM
To: Chin, Bill; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: Fwd: Invite Confirmations for September 18th as of today

This looks like the same tally Bill already knew about. Can I help with Pfizer?

Sent from my iPhone

Begin forwarded message:

From: "Cradic, Amy" (b) (6)
Date: September 11, 2017 at 2:21:31 PM EDT
To: "Collins, Francis (NIH/OD) [E]" (b) (6) "Gottlieb, Scott" (b) (6)
Subject: Invite Confirmations for September 18th as of today

Dr. Collins and Dr. Gottlieb:

Here are the responses to date for the meeting attendance. Please let me know if there is additional outreach you'd like me to make. I will send a draft agenda shortly. Regards, Amy

CEOs Confirmed:

Celgene
Eisai
Eli Lilly

Otsuka
Purdue Pharma

Senior Execs Confirmed:

Bristol Meyers
Merck
Allergen (COO)
Novartis

CEO invite response pending

Pacira
J&J
Novo Nordisk
Chromocell
Pfizer
Braeburn

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 19:25:33 +0000
To: Myles, Renate (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]
Subject: RE: [REDACTED] (b) (4)

[REDACTED] (b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
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fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, October 11, 2017 3:05 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)
Subject: RE: [REDACTED] (b) (4)

I just received the attached email [REDACTED] (b) (4). They cleared the release with no changes, and said they should have a quote to me in the next 15 minutes. Rep will be:

[REDACTED] (b) (4)

Still waiting on a quote from the Acting Secretary.

From: Wholley, David (FNIH) [T]
Sent: Wednesday, October 11, 2017 3:00 PM
To: Myles, Renate (NIH/OD) [E] [REDACTED] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)
Subject: [REDACTED] (b) (4)
Importance: High

[REDACTED] (b) (4)

Please let me know if I may be of further assistance. David

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From: Wholley, David (FNIH) [T]
Sent: Thu, 24 Aug 2017 13:57:52 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wilder, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: McManus, Ayanna (NIH/OD) [E]; Walker, Paula (NIH/NINDS) [E]; Simon, Dina (NIH/OD) [C]; Schulke, Hilda (NIH/NIDA) [E]; Hardesty, Rebecca (NIH/OD) [C]; Schwetz, Tara (NIH/OD) [E]; NIHDirectorMeetings; Melencio, Cheryl (FNIH) [T]
Subject: RE: Meeting materials: tomorrow's 8-24-2017 opioid initiative meeting

I will call in. David

David Wholley
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From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, August 23, 2017 9:34 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wilder, Elizabeth (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: McManus, Ayanna (NIH/OD) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6); Simon, Dina (NIH/OD) [C] (b) (6); Schulke, Hilda (NIH/NIDA) [E] (b) (6); Hardesty, Rebecca (NIH/OD) [C] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: Meeting materials: tomorrow's 8-24-2017 opioid initiative meeting

Good evening,

Please find attached materials for tomorrow's 1 pm meeting to discuss the NIH opioid and pain initiative.

This will be the first in a series of regular meetings to chart out the partnership and initiative plans. David and Betsy, apologies for the very late notice. We hope you can join us either in person or by phone!

The meeting will be held in Building 1/Room 116, and teleconference information is below:

Dial In: (b) (6)

Participant Code: (b) (6)

Please let me know if you have any questions.

Thank you,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Thu, 17 Aug 2017 15:39:57 +0000
To: Stein, Jack (NIH/NIDA) [E]; Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: RE: Message to Hever members

I agree, great job. While it is good be comprehensive, I am a little concerned that the list of "partnerships" is too long and the language a bit prescriptive. It may well be that some of the ideas proposed lend themselves to a classic PPP in the AMP model and some do not. We'd want the industry leaders to feel they have some say in that. Please see my suggested changes below.

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From: Stein, Jack (NIH/NIDA) [E]
Sent: Thursday, August 17, 2017 8:56 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)v>; Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Message to Hever members

Francis -

This reads quite nicely! 2 minor suggestions/questions:

1. Referring to the partnership may imply sequential development and rollout hence perhaps simply say we are proposing 2 partnerships (or 2 types or partnership models?).
2. The first partnership doesn't mention the research network though implementation research is critical component. Should we add?

I proposed some edits in parentheses below.

Lastly since this is being presented as partnership with FDA I assume it will be run by them prior to sending.

Thanks

Jack

NIH is now proposing a two part partnership. [proposing two partnerships?]. [One partnership will focus on] The first piece will be focused on developing [and testing] new formulations and combinations of medications to treat opioid use disorders, and to prevent and reverse overdose. NIH will prioritize its own portfolio for basic science aspects of this work, and will work with biotechnology companies and FDA, primarily through enhancement of existing partnerships, although we welcome additional interest. [In addition we will explore ways to study implementation of these new products via a clinical research network building on existing NIH infrastructures.]

Sent with BlackBerry Work
(www.blackberry.com)

From: Collins, Francis (NIH/OD) [E] (b) (6)
Date: Thursday, Aug 17, 2017, 6:57 AM
To: Wolinetz, Carrie (NIH/OD) [E] (b) (6), Tabak, Lawrence (NIH/OD) [E] (b) (6), Volkow, Nora (NIH/NIDA) [E] (b) (6), Koroshetz, Walter (NIH/NINDS) [E] (b) (6), Stein, Jack (NIH/NIDA) [E] (b) (6), Baker, Rebecca (NIH/OD) [E] (b) (6), Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Subject: Message to Hever members

Hi all,

With thanks to Carrie for providing an excellent draft, here's what I propose to send to Hever.

Comments?

FC

Dear Hever Group colleagues,

I am writing to follow up on our spring conversations about addressing the opioid crisis and to ask for your willingness to participate in the next steps of development of a public-private partnership opportunity with NIH and FDA. Following the last Hever meeting, and informed by your responses to queries sent to you in April and May, NIH has held a series of three cutting-edge scientific workshops which brought together innovative experts from government, academia, and industry, including representatives from several of your companies.

With insights from these meetings, NIH is now proposing a two part partnership action plan. The first piece will be focused on developing new formulations and combinations of medications to treat opioid use disorders, and to prevent and reverse overdose. NIH will prioritize its own portfolio for basic science aspects of this work, and will work with biotechnology companies and FDA, primarily through enhancement of existing partnerships, although we welcome additional interest.

The second project will be focused on accelerating development of new, non-addictive pain therapies through partnerships between NIH, FDA, and the private sector. It is this set of opportunities ~~opportunity~~ for which ~~that~~ I hope you will join in helping us develop a specific workplan. We anticipate this project could ~~will~~ involve: working with FDA on accelerated review of novel analgesics; developing biomarkers ~~development~~ to identify subsets of patients with varying responses to pain treatments;

establishing a data and information sharing collaborative between industry groups, with NIH serving as an honest broker, to learn from common efforts and accelerate late stage compounds; development of an objective nociometer (a "Pain-o-meter") for pain assessment and response to interventions that will empower patients and facilitate the testing of new drugs; and access to a NIH-sponsored clinical research network. Operationally, we imagine ~~such a~~ one or more of these partnerships could be effectively managed by the Foundation for NIH, in a somewhat analogous fashion to the Accelerating Medicines Partnership.

In addition to reaching out to all of you now, my colleagues and I intend to present this opportunity at the PhRMA Biomedical Advisory Council (BMAC) meeting in mid-September, at the invitation of Bill Chin. Shortly after the BMAC meeting, Governor Chris Christie, who is leading the President's Commission on Combatting Drug Addiction and the Opioid Crisis, is planning to convene pharmaceutical company CEOs to enlist their help in the government-wide effort to address this national emergency. Such a meeting would seem to provide an opportune time to promote the development of a partnership.

The sense of urgency to make rapid progress in the face of the current expanding epidemic cannot be overemphasized. I hope you will join with NIH, FDA, and FNIH in developing a workplan for a successful partnership to move forward.

Specifically, I would like to have your responses to two questions: 1) Are you willing to take part in the next steps of developing a specific workplan on accelerating development of new, non-addictive pain therapies? 2) If so, can you identify a point person in your organization who could take part in a face to face meeting this fall?

Please send responses to me (with cc to (b) (6)) by September 1.

Francis

From: Wholley, David (FNIH) [T]
Sent: Sun, 9 Jul 2017 20:36:04 -0400
To: Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: Re: MS Program

Thanks Francis. Will keep you in the loop as we hear back from Verily on their proposed way forward.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, July 9, 2017 12:45 PM
To: Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: FW: MS Program

Hi David and Walter,

Andy Conrad wanted me to see the data they have generated with wearable sensors and MS – as part of his motivation for wanting to see more of these data included in AMP-PD. Please see attached; best not to distribute further.

FC

From: Linda Boorman [REDACTED] (b) (6)
Sent: Friday, July 07, 2017 3:03 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)
Cc: Solomon, Shira [REDACTED] (b) (6)
Subject: MS Program

Hi Dr. Collins,

Andy asked me to forward the attached document to you.

Take care,

--

Linda Boorman | [REDACTED] (b) (6)

Verily

From: Wholley, David (FNIH) [T]
Sent: Thu, 19 Oct 2017 02:53:45 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: Re: New PPPs for pain meds and OUD treatment

Yes, and is he ok with inviting them to call on Friday (he should be--lets just make sure no issues)

Sent from my BlackBerry 10 smartphone.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, October 18, 2017 10:32 PM
To: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: RE: New PPPs for pain meds and OUD treatment

Happy to inform Bill – the news is that Ellen, Celia and Allison will serve as FDA liaisons?

Thanks,
Rebecca

From: Wholley, David (FNIH) [T]
Sent: Wednesday, October 18, 2017 5:24 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: FW: New PPPs for pain meds and OUD treatment

All: As promised from my conversation on Monday with Janet Woodcock. Should these folks be invited to Friday's call? If so, should Rebecca be the one to let Bill Chin know? Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
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fnih.org

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From: Hertz, Sharon H (b) (6)
Sent: Wednesday, October 18, 2017 4:59 PM
To: Wholley, David (FNIH) [T] (b) (6)
Cc: Winchell, Celia J (FDA/CDER) (b) (6); Fields, Ellen (FDA/CDER) (b) (6)
Subject: New PPPs for pain meds and OUD treatment

Hi,

After discussing this with Dr. Woodcock, I am reaching out to let you know that Ellen Fields will be participating as the primary representative for the new pain meds PPP and Celia Winchell for the OUD treatment PPP. Allison Lin will also be participating from our division.

Thank you,
Sharon

Sharon Hertz, MD
Division Director
Division of Anesthesia, Analgesia, and Addiction Products
FDA/CDER
HFD-170, WO 22, Rm (b) (6)
10903 New Hampshire Ave.
Silver Spring, MD 20993

(b) (6)
(b) (6) Fax

From: Wholley, David (FNIH) [T]
Sent: Fri, 8 Dec 2017 21:14:55 +0000
To: Flores, Christopher [CONUS]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
Subject: RE: Can you co-lead the final meeting summary session next week with Francis Collins?

Great!! We (you, Francis, us) can huddle sometime after the end of day 1 festivities to take stock and figure out how to work this out. Thanks so much for all your helpful involvement in our efforts so far—they've really made a difference.

From: Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]
Sent: Friday, December 8, 2017 3:45 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Francis Collins (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: RE: Can you co-lead the final meeting summary session next week with Francis Collins?

Happy to, David.

See you all next week,
Chris

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, December 08, 2017 3:34 PM
To: Flores, Christopher [CONUS] <CFlores2@its.jnj.com>
Cc: Francis Collins (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: Can you co-lead the final meeting summary session next week with Francis Collins?

Dear Chris,
In going over the final meeting agenda for next week's meeting on the opioids partnership with Francis Collins he asked if you might co-lead with him the final talk summarizing the major findings and action items of the two days on the afternoon of Dec. 13. We (FNIH) would summarize major points on powerpoint as we go along and have that available to you both after the final break to support your joint presentation and any ensuing discussion. Can you please let us know as soon as possible if you'd be willing to do this?

Thanks,
David Wholley

Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Mon, 18 Sep 2017 13:43:08 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Cash for planning?

(b) (4)

Sent from my BlackBerry 10 smartphone.

Original Message

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, September 18, 2017 9:01 AM
To: Wholley, David (FNIH) [T]
Subject: Cash for planning?

(b) (4)

FC

Sent from my iPhone

From: Wholley, David (FNIH) [T]
Sent: Wed, 16 Aug 2017 02:04:49 +0000
To: Wolinetz, Carrie (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E]
Subject: RE: conversation with Amy Cradic (Gov. Christie's CoS)

(b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
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fnih.org

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From: Wolinetz, Carrie (NIH/OD) [E]
Sent: Tuesday, August 15, 2017 5:19 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6)
Subject: Re: conversation with Amy Cradic (Gov. Christie's CoS)

Timing seems like it would work ok. I guess my biggest question is whether their "normal" list of NJ CEOs would make sense for the projects being discussed. To David's point this morning, might be a strange conversation with a CEO whose company doesn't have equity in the pain space. (b) (5)

On that last part, wonder if we should share something similar with the Commission as we did w/FDA (budget free summary)?

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and

Associate Director for Science Policy
Office of the Director
National Institutes of Health

(b) (6)

----- Original message -----

From: "Collins, Francis (NIH/OD) [E]" (b) (6)

Date: 8/15/17 4:17 PM (GMT-05:00)

To: "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Volkow, Nora (NIH/NIDA) [E]"

(b) (6), "Koroshetz, Walter (NIH/NINDS) [E]" (b) (6)

"Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Stein, Jack (NIH/NIDA) [E]"

(b) (6) "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Burklow, John

(NIH/OD) [E]" (b) (6) "Hallett, Adrienne (NIH/OD) [E]" (b) (6)

"Wholley, David (FNIH) [T]" <dwholley@fni.org>

Cc: "Wood, Gretchen (NIH/OD) [E]" (b) (6)

Subject: conversation with Amy Cradic (Gov. Christie's CoS)

Hi all,

I just spoke with Amy Cradic about the proposed NJ industry opioid meeting that Gov. Christie wants to convene. Here's the scoop:

- The Governor would invite CEOs. She will send a list of those with strong NJ connections that they would normally include.
- She thinks it would be a closed meeting with the Governor, CEOs, NIH, and maybe FDA.
- There could then be a joint public statement released to the press – probably CEOs won't want to hold a press conference because the questions would likely be unfriendly (drug pricing, blame for opioids, etc.)
- She understands we would want this to happen after the PhRMA BMAC meeting (9/11 or 12) but doesn't want it to be too close to October 1, when the Commission final report is due. So she pressed for the week of 9/18. We should avoid 9/20-22 because of Rosh Hashanah, so this would lead to focusing on 9/18 or 9/19.
- The meeting would likely be in Trenton or Philly, near Amtrak.

How does that all sound? I'm not sure what delegation we should arrange, but what is the availability of Nora and Walter for 9/18 or 9/19? (Miraculously I could make either of those work.)

ALSO PLEASE NOTE: Amy said she would welcome any input from NIH and FDA about specifics we would want to see included in the Commission final report. We should discuss what to include in this.

Thoughts?

FC

From: Wholley, David (FNIH) [T]
Sent: Mon, 20 Nov 2017 19:33:43 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]
Subject: RE: Conversation with industry participants from both focus areas: week of Dec 4?

Hi Francis,
We had already agreed to such a call – it is on the revised workgroup meeting schedule I sent for last week's check-in call. Plan is to get the co-chairs' schedules first and invite anyone else who wants to join from there. Right now we are looking at Dec 6, 7, or 8. Will let you know soon as we have some more availability data.
David

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, November 20, 2017 12:19 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)
Subject: Conversation with industry participants from both focus areas: week of Dec 4?

Hi David,

I understand that the consultation process is now underway with the three working groups in the pain focus area, and things are off to an excellent start. Thank you for all the work of your team to get these groups off the ground.

I am also thinking hard about December 11, when it will be important to present a cohesive whole about the partnership for the PhRMA Board meeting, especially since we hope this will be an occasion where the CEOs might be willing to make some financial commitments.

Would it be possible to convene the industry reps (or at least the co-chairs?) for both project 1 and project 2 by teleconference during the week of December 4, in order to prepare optimally for the PhRMA presentation on December 11?

Please let me know what you think.

Thanks, Francis

From: Wholley, David (FNIH) [T]
Sent: Mon, 20 Nov 2017 20:31:41 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]
Subject: RE: Conversation with industry participants from both focus areas: week of Dec 4?

PS, we are working around it but the biggest challenge seems to be some kind of NIH pain meeting on the 8th and 9th...

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, November 20, 2017 2:59 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6);
Subject: RE: Conversation with industry participants from both focus areas: week of Dec 4?

Great, thanks!

From: Wholley, David (FNIH) [T]
Sent: Monday, November 20, 2017 2:34 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6);
Subject: RE: Conversation with industry participants from both focus areas: week of Dec 4?

Hi Francis,

We had already agreed to such a call – it is on the revised workgroup meeting schedule I sent for last week's check-in call. Plan is to get the co-chairs' schedules first and invite anyone else who wants to join from there. Right now we are looking at Dec 6, 7, or 8. Will let you know soon as we have some more availability data.

David

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, November 20, 2017 12:19 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Porter, Linda (NIH/NINDS) [E] (b) (6)

Subject: Conversation with industry participants from both focus areas: week of Dec 4?

Hi David,

I understand that the consultation process is now underway with the three working groups in the pain focus area, and things are off to an excellent start. Thank you for all the work of your team to get these groups off the ground.

I am also thinking hard about December 11, when it will be important to present a cohesive whole about the partnership for the PhRMA Board meeting, especially since we hope this will be an occasion where the CEOs might be willing to make some financial commitments.

Would it be possible to convene the industry reps (or at least the co-chairs?) for both project 1 and project 2 by teleconference during the week of December 4, in order to prepare optimally for the PhRMA presentation on December 11?

Please let me know what you think.

Thanks, Francis

From: Wholley, David (FNIH) [T]
Sent: Mon, 23 Oct 2017 11:40:24 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Draft of slides for discussion on tomorrow's AMP EC pre-call

We know! The usual challenge
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, October 22, 2017 9:23 PM
To: Wholley, David (FNIH) [T]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]
Cc: Hoffmann, Steve (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Vardanian, Lilit (FNIH) [T]; Canet-Aviles, Rosa (FNIH) [T]; Cush, Stephanie (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Morgan, Emily (FNIH) [T]
Subject: RE: Draft of slides for discussion on tomorrow's AMP EC pre-call

Looking forward to discussing tomorrow. Presentations may need to be trimmed a bit to allow discussion on Friday.

FC

From: Wholley, David (FNIH) [T]
Sent: Sunday, October 22, 2017 8:51 PM
To: McManus, Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Hoffmann, Steve (FNIH) [T] <shoffmann@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Vardanian, Lilit (FNIH) [T] <lvardanian@fnih.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Cush, Stephanie (FNIH) [T] <scush@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>
Subject: Draft of slides for discussion on tomorrow's AMP EC pre-call
Importance: High

This is what I have so far for tomorrow's call. Still awaiting review/inputs from some of the co-chairs. Look forward to our discussion.

FYI I will be out of town at a family wedding on Friday October 27. Expect I will be able to call in and moderate the EC call, but if for any reason I am unable to (it will be 6AM where I am, and not a familiar environment) Joe Menetski is prepared to lead the call from the FNIH side without me.

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Tue, 17 Oct 2017 15:59:09 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Allen-Gifford, Patrice (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: RE: email drafts for opioids partnership

Great. Rebecca said she would work with your calendar. I will try to work my schedule around whatever is selected.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 17, 2017 6:56 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Allen-Gifford, Patrice (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: RE: email drafts for opioids partnership

Hi David,

These drafts all look great to me. As I am out of pocket, I am asking Rebecca to work with Gretchen and/or Exec Sec to get these sent out from my e-mail today. We need to nail down the time for the 90 minute Friday call right away. To be nice to those in Europe or the west coast, an 11 AM call might be best.

FC

From: Wholley, David (FNIH) [T]
Sent: Tuesday, October 17, 2017 12:29 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: email drafts for opioids partnership

Francis,

Here are the emails I have composed for

1. (b) (5) the lead industry co-chair identified by Walter and Linda for Focus Area #2. Note that we are still waiting to see if Nora wants an industry co-chair for area #1.
2. Invitation to all industry reps to participate in the partnership generally and the Friday call specifically. Note you may need to adjust how logistics info for the call is handled—I think we will need Rebecca's help here. The note would be sent to the attendees on the lists provided to Rebecca by Bill Chin.
3. An invitation to academic invitees to work on focus area #2 who attended one of the NIH workshops over the summer. Again, we would need to see Nora's plan and whether she wants such invitees for focus area 1 before proceeding.
4. An invitation to academic invitees to work on focus area #2 who did NOT attend any of the NIH workshops and are newer to the process.

The academic invitees for notes 3 and 4 are:

(b) (5)

We are working to find their email addresses, but I am copying Linda Porter to see if she can provide them faster. Linda, I assume Francis should start with (b) (5)

(b) (5) and then based on the outcome of Friday's call we can invite (b) (5)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Wholley, David (FNIH) [T]
Sent: Wed, 20 Dec 2017 13:53:56 +0000
To: Baker, Rebecca (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]
Cc: Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]
Subject: RE: FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH

Thanks, Rebecca. If I may add one thing, it would be just a reminder that PhRMA wants this one kept very brief. The original suggested length was two pages, and we're over that already. So if you want to insert something of any length, I would ask that you show where something of corresponding length should be taken out. Also, it would be helpful if you could make your suggested changes as redlines rather than general comments. Thanks, David

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, December 20, 2017 8:39 AM
To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Porter, Linda (NIH/NINDS) [E]
(b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6) Stein, Jack (NIH/NIDA) [E] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>
Subject: FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH

Good morning,

As follow up to last week's partnership design meeting, FNIH has drafted the attached summary to share with the PhRMA Biomedical Advisory Council.

PhRMA has asked for a draft by COB today. Could you please review and send your revisions and edits by 4 PM today? Please be sure to copy David and Mike.

Thank in advance for your thoughts,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Tuesday, December 19, 2017 7:38 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>
Subject: Opioid PPP update for BMAC 12-19-17 draft for NIH

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his

introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Mon, 27 Nov 2017 21:47:50 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: Re: FDA Meeting on December 11-12

Ok, thanks.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, November 27, 2017 1:46 PM
To: Wholley, David (FNIH) [T]
Cc: Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: FDA Meeting on December 11-12

That's fine as long as you are sure we will have good representation from the companies involved in focus area 1 on the morning of the 12th.

FC

From: Wholley, David (FNIH) [T]
Sent: Monday, November 27, 2017 11:53 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: FW: FDA Meeting on December 11-12

Please see below. I think we stick to our original plan of kicking this off with focus area 1 on the morning of day 1 (12th), then going to pain on that afternoon of day 1 and continuing the discussion the following day (13th). We can include the key conclusions from focus area 1 discussion in the sum-up at the end of day 2 (of course). Let me know what you think.

From: Hertz, Sharon H (b) (6)
Sent: Monday, November 27, 2017 11:30 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: FDA Meeting on December 11-12

Thanks, that is a great idea except Ellen will be covering the division while I am at the FDA meeting. I understand that it is difficult to move meetings with so many people.

I don't think you need to change the agenda for the meeting. Both areas are important, so I'll just have to miss whichever is on the 12th.

Sharon

Sharon Hertz, MD
Division Director
DAAAP
(b) (6)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]
Sent: Monday, November 27, 2017 11:18 AM
To: Hertz, Sharon H (b) (6)
Cc: Biarnes, Michael C (NIH) <mbiarnes@fnihi.org>; Menetski, Joseph M (NIH) <jmenetski@fnihi.org>
Subject: RE: FDA Meeting on December 11-12

What if we did pain on the 12th and delayed focus area 1 (addiction and overdose) discussions to the morning of day 2 (the 13th). Am assuming someone like Ellen Fields might be able to make both the 12th and 13th, and provide some continuity. Would that work?

From: Hertz, Sharon H (b) (6)
Sent: Monday, November 27, 2017 9:17 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>
Subject: RE: FDA Meeting on December 11-12

It is some of the companies. I don't know if it is the same people or not, but there are many issues that could impact the drug and device companies so we expect many to attend. Beyond that, many of us at FDA are conflicted. For example, Doug Throckmorton and I are speaking/moderating on the 12th. We can have people cover, but I'm sure you understand that it is very difficult to have continuity from us if different people attend meetings on the same topic.

Sharon

Sharon Hertz, MD
Division Director
DAAAP
(b) (6)

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]
Sent: Sunday, November 26, 2017 1:09 PM
To: Hertz, Sharon H (b) (6)

Cc: Biarnes, Michael C (NIH) <mbiarnes@fnih.org>; Menetski, Joseph M (NIH) <jmenetski@fnih.org>
Subject: FDA Meeting on December 11-12

Hi Sharon—

On one of our opioid partnership calls last week you brought up a concern that our face to face meeting scheduled for December 12-13 will conflict with a meeting FDA is planning to hold on Dec 11-12. I did speak to NIH leadership about this and they are concerned there are other conflicts, making moving the dates of the 12-13th meeting. In looking up the FDA meeting on the Federal Register, I notice it is specifically to discuss Packaging, Storing, and Disposal Options to Enhance Opioid Safety. Given this I am not sure of the degree of overlap with our planned meeting. I can see where some of the same companies would attend both meetings, but do you anticipate it will be the same actual personnel from those companies? And would the conflicts apply equally to the representatives and companies attending the current pain focus area discussions, or is it mainly a concern with respect to the companies associated with the addiction and overdose focus area currently led by NIDA? If the latter, though not optimal we could consider arranging the agenda for the 12-13 to put the addiction and overdose discussions on the second day. Please let me know. David

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Fri, 8 Sep 2017 13:23:10 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]
Cc: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

No, roundtable is the appropriate word, but it is now the only thing suggested. And if talk is all we suggest, that is all we are likely to get.
Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Friday, September 8, 2017 8:34 AM
To: Wholley, David (FNIH) [T]
Cc: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Ken Verburg did propose that the company folks would sit around the table and share lessons learned. the somewhat radical idea is that they could prevent companies from wasting time and money doing things that already failed for another. Data sharing of company data for data mining was next piece which led to the point that they would exclude the parasites- ie. those that take but don't put up their data.
SItting around the table was the phrase , is "roundtable" the wrong word????

Walter J Koroshetz MD
Director, National Institute of Neurological Disorders and Stroke/NIH
Sent from my iPhone

On Sep 8, 2017, at 8:02 AM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Walter, thanks for adding specificity to some of these. I don't recall however that the proposed data sharing involved just a roundtable--which sounds like a discussion--but an actual database.
Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Thursday, September 7, 2017 9:08 PM
To: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wholley, David (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Thanks so much Rebecca. Nice job as usual. Please find suggestions for edits.

Best wishes,

Walter

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Thursday, September 07, 2017 4:20 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E]
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>;
Wolinetz, Carrie (NIH/OD) [E] (b) (6)>
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6)>
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest
matrix

Rebecca this is a very good summary. The only other item that is not listed but that was brought up by the participants was that REGULATORY PATHWAYS and how PPP could be used for FDA to help pharma. Though how one would construct such a facilitatory role in a PPP is not completely clear. nora

From: "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Date: Thursday, September 7, 2017 at 1:48 PM
To: Francis Collins (b) (6); "Tabak, Lawrence (NIH/OD) [E]"
(b) (6); Nora Volkow (b) (6); Walter Koroshetz
(b) (6); Jack Stein (b) (6); "Porter, Linda (NIH/NINDS) [E]"
(b) (6); "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>; "Wolinetz, Carrie
(NIH/OD) [E]" (b) (6)
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)
Subject: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest
matrix

Good afternoon,

As discussed at this morning's meeting, and with thanks to David and Jack, please find attached a draft matrix to solicit input from potential private sector partners on ideas for a PPP. This matrix would be circulated with today's meeting participants, and used to generate an anonymized tally of high-priority ideas for a PPP effort. We have tried to allow space for comments, but please weigh in on ways to solicit helpful ideas.

We are hoping to send this out when memories are fresh, and in time to inform the 9/11 PhRMA meeting. Thank you in advance for your quick turnaround suggested edits.

Best,

Rebecca

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, September 6, 2017 4:58 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>;
Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E]
(b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke,
Hilda (NIH/NIDA) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6);
Hardesty, Rebecca (NIH/OD) [C] (b) (6); Melencio, Cheryl (FNIH) [T]
<cmelencio@fnih.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6); Wood, Gretchen
(NIH/OD) [E] (b) (6)
Subject: Meeting materials: tomorrow's 9- 7- 2017 opioid and pain partnership planning meeting

Good afternoon,

Please find attached materials for tomorrow's teleconference in preparation for the Sept 11 Pain and Opioid Initiative Planning Meeting with PhRMA and industry colleagues.
The NIH team will gather at 7AM in Building 1, Room 116 for the presentation and discussion.
I will bring hard copies of all materials, and the slides will also be shared via Webex.

Please let me know if you have any questions or concerns.

Thank you and see you tomorrow,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Fri, 8 Sep 2017 12:02:38 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Walter, thanks for adding specificity to some of these. I don't recall however that the proposed data sharing involved just a roundtable--which sounds like a discussion--but an actual database. Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Thursday, September 7, 2017 9:08 PM
To: Volkow, Nora (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wholley, David (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: RE: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Thanks so much Rebecca. Nice job as usual. Please find suggestions for edits.
Best wishes,

Walter

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Thursday, September 07, 2017 4:20 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: Re: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Rebecca this is a very good summary. The only other item that is not listed but that was brought up by the participants was that REGULATORY PATHWAYS and how PPP could be used for FDA to help pharma. Though how one would construct such a facilitatory role in a PPP is not completely clear. nora

From: "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Date: Thursday, September 7, 2017 at 1:48 PM
To: Francis Collins (b) (6); "Tabak, Lawrence (NIH/OD) [E]" (b) (6); Nora Volkow (b) (6); Walter Koroshetz (b) (6)

(b) (6) Jack Stein (b) (6), "Porter, Linda (NIH/NINDS) [E]"
(b) (6)>, "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Wolinetz, Carrie
(NIH/OD) [E]" (b) (6)

Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)

Subject: Follow up to 9- 7- 2017 opioid and pain partnership planning meeting: industry interest matrix

Good afternoon,

As discussed at this morning's meeting, and with thanks to David and Jack, please find attached a draft matrix to solicit input from potential private sector partners on ideas for a PPP. This matrix would be circulated with today's meeting participants, and used to generate an anonymized tally of high-priority ideas for a PPP effort. We have tried to allow space for comments, but please weigh in on ways to solicit helpful ideas.

We are hoping to send this out when memories are fresh, and in time to inform the 9/11 PhRMA meeting. Thank you in advance for your quick turnaround suggested edits.

Best,

Rebecca

From: Baker, Rebecca (NIH/OD) [E]

Sent: Wednesday, September 6, 2017 4:58 PM

To: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E]

(b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] <(b) (6) Porter,
Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>;
Wolinetz, Carrie (NIH/OD) [E] (b) (6)

Cc: Schwetz, Tara (NIH/OD) [E] (b) (6) McManus, Ayanna (NIH/OD) [E]

(b) (6) NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke,
Hilda (NIH/NIDA) [E] (b) (6)>; Walker, Paula (NIH/NINDS) [E] (b) (6)
Hardesty, Rebecca (NIH/OD) [C] (b) (6)>; Melencio, Cheryl (FNIH) [T]
<cmelencio@fnih.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6) Wood, Gretchen
(NIH/OD) [E] (b) (6)

Subject: Meeting materials: tomorrow's 9- 7- 2017 opioid and pain partnership planning meeting

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The NIH team will gather at 7AM in Building 1, Room 116 for the presentation and discussion.
I will bring hard copies of all materials, and the slides will also be shared via Webex.

Please let me know if you have any questions or concerns.

Thank you and see you tomorrow,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Thu, 10 Aug 2017 14:11:12 +0000
To: Collins, Francis (NIH/OD) [E]; 'Dolsten, Mikael'; Hodes, Richard (NIH/NIA) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; 'Lifton, Richard'; 'Lundberg, Jan'; Rodgers, Griffin (NIH/NIDDK) [E]; 'Stoffels, Paul'; Tabak, Lawrence (NIH/OD) [E]; Terry, Sharon MA
Cc: Boskent, Celeste (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Craver, Stephanie (NIH/NIAMS) [E]; Doswell, Greta (NIH/OD) [E]; 'Edmonds, Pamela'; Yuliya Ilchik; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Meltzer, Sherry (NIH/NIAMS) [E]; 'Poniente, Josefina'; Poole, Charlene (NIH/NIDDK) [C]; 'Protasiewicz, Ann'; Walker, Paula (NIH/NINDS) [E]; Wood, Gretchen (NIH/OD) [E]; 'Zanellato, Ann'; Canet-Aviles, Rosa (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Lea, Allison (NIH/OD) [E]; Canet-Aviles, Rosa (FNIH) [T]
Subject: RE: Nomination for private sector Co-Chair for the AMP Parkinson's Disease Steering Committee - ACTION REQUESTED

Dear Executive Committee members:

Just a reminder concerning the request below. I have heard back positively from several of you, and am conscious that August is a difficult time to get everyone's input. I propose we give this until tomorrow cob, and unless I have heard any compelling number of negative responses, assume approval and move forward.

Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Friday, July 28, 2017 7:58 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); 'Dolsten, Mikael' <mikael.dolsten@pfizer.com>; Hodes, Richard (NIH/NIA) [E] (b) (6); Katz, Stephen I. (NIH/NIAMS) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); 'Lifton, Richard' <rickl@rockefeller.edu>; 'Lundberg, Jan' <lundberg_jan@lilly.com>; Rodgers, Griffin (NIH/NIDDK) [E] (b) (6); 'Stoffels, Paul' <PStoffe4@its.jnj.com>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Terry, Sharon MA <sterry@geneticalliance.org>
Cc: Boskent, Celeste (NIH/OD) [E] (b) (6); Bronson, Charlette (NIH/NIA) [E] (b) (6); Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6); Craver, Stephanie (NIH/NIAMS) [E] (b) (6); Doswell, Greta (NIH/OD) [E] (b) (6); 'Edmonds, Pamela' <edmonds_pamela_j@lilly.com>; Yuliya Ilchik <yilchik@geneticalliance.org>; McManus, Ayanna (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Meltzer, Sherry (NIH/NIAMS) [E] (b) (6); 'Poniente, Josefina' <ponienj@mail.rockefeller.edu>; Poole, Charlene

(NIH/NIDDK) [C] <PooleC@EXTRA.NIDDK.NIH.GOV>; 'Protasiewicz, Ann' <ann.protasiewicz@pfizer.com>; Walker, Paula (NIH/NINDS) [E] (b) (6)>; Wood, Gretchen (NIH/OD) [E] (b) (6); 'Zanellato, Ann' <AZanell2@its.jnj.com>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>; Gadbois, Ellen (NIH/OD) [E] (b) (6) Lea, Allison (NIH/OD) [E] (b) (6)

Subject: Nomination for private sector Co-Chair for the AMP Parkinson's Disease Steering Committee - ACTION REQUESTED

Dear AMP Executive Committee Members:

As we near completion of the final research plan and launch of the AMP initiative in Parkinson's disease, I am **asking for your approval of the inaugural private sector Co-chair of the AMP AD Steering Committee.**

As we have in forming the other AMP Steering Committees, FNIH has polled the representatives of the five private sector organizations currently committed to supporting AMP PD (GSK, the Michael J. Fox Foundation, Pfizer, Sanofi, and Verily) and has received one (b) (5) at the face to face project planning meeting we held in June alongside her colleague Rita Balice-Gordon, and has been involved in reviewing and approving the final plan. Rita's nomination contained the following recommendation: (b) (5)

Rita has asserted that (b) (5) is willing to serve and would have internal approvals to do so. We have also consulted with our colleagues at NINDS concerning (b) (5)'s nomination, and they are very supportive. (b) (5) would serve alongside Marg Sutherland, Program Director at NINDS, who will be the SC Co-chair from NIH. (b) (5) biosketch is attached.

Can you please let me know by return email to this address whether or not you approve (b) (5) appointment as AMP Parkinson's Disease Steering Committee Co-Chair no later than next Friday, August 4? Your timely input would be most appreciated.

Regards,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnihi.org

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From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Dec 2017 18:28:43 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: note for Janet
Attachments: Opioids Design Phase F2F Dec 2017 Agenda - DRAFT 05Dec2017.docx

Here you go

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, December 5, 2017 1:04 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Subject: RE: note for Janet

Trying that again - I'm pretty sure Janet will ask to see the agenda for Dec. 12 and 13, in order to decide which parts she might be able to attend. Can you send that?

FC

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, December 05, 2017 1:03 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Subject: RE: note for Janet

Tyhan,

From: Wholley, David (FNIH) [T]
Sent: Tuesday, December 05, 2017 10:39 AM
To: Collins, Francis (NIH/OD) [E] <c[REDACTED]@fnihi.org> (b) (6)
Subject: note for Janet

Francis—draft note you requested below

Hi Janet –

I am writing to check in with you about the Opioids Partnership in-person meeting that FNIH is holding on December 12-13 next week at the Bethesda Marriott. We did our best to find dates that would work, but inevitably conflicts arise, and one of these apparently is a meeting that FDA is holding on packaging and disposal standards for opioids on December 11 and 12. My understanding is that this could have affect FDA attendance on the 12th in particular, involving schedules of Sharon Hertz and Ellen Fields in particular. I think reasonably senior FDA involvement would be important to send the right signal to the public and to our industry partners in particular. In that light, would you be willing to be there on the 12th? If not, can you help identify someone suitable to represent FDA at this critical juncture in our efforts?

Regards,
Francis

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*



Partnership to Address the Opioid Crisis Face-to-Face Meeting

Bethesda North Marriott Hotel – 5701 Marinelli Road, Rockville, MD 20852

Tuesday December 12th – 7:30 AM – 6:30 PM

Wednesday December 13th – 7:30 AM – 4:00 PM

Agenda

December 12th

WEBEX TO BE ADDED

Meeting number (access code):

Meeting password:

- | | |
|----------------------------|---|
| 7:30 am – 8:00 am | Registration and Breakfast |
| 8:00 am – 8:15 am | Agenda Overview, Meeting Logistics
<i>David Wholley (FNIH)</i> |
| 8:15 am – 8:30 am | Welcome and Introduction
<i>Francis Collins (NIH)</i> |
| 8:30 am – 8:45 am | Overview of Focus Area A
<i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i> |
| 8:45 am – 9:00 am | Overview of Focus Area B
<i>Walter Koroshetz (NINDS) [David Wholley (FNIH)]</i> |
| 9:00 am – 12:30 pm | Focus Area A: OUD Treatment and Overdose Prevention/Reversal
<i>Co-Chairs: Christopher Flores (J & J Consumer); Osman Cigeroglu (Pfizer)</i> |
| 9:00 am – 10:00 am | New Formulations/Combinations of Existing OUD Medications
<i>TBD</i> |
| 10:00 am – 10:15 am | Break |
| 10:15 am – 11:15 am | More Potent/Longer-lasting Antagonists to Reverse Overdose
<i>TBD</i> |
| 11:15 am – 12:15 pm | Alternative Endpoints for OUD Medications
<i>TBD</i> |



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Agenda

12:15 pm – 12:30 pm Focus Area A: Next Steps and Timelines for White Paper Development
TBD

12:30 pm – 1:00 pm Lunch

1:00 pm – 5:30 pm Focus Area B: Development of New Pain Medications Working Groups

1:00 pm – 3:00 pm Asset Repurposing Working Group
Co-Chairs – Chris Austin (NCATS), Chris Flores (Johnson & Johnson)

3:00 pm – 3:15 pm Break

3:15 pm – 5:15 pm Clinical Trials Network Working Group
Co-Chairs - Linda Porter (NINDS), Kenneth Verburg (Pfizer), Clinton Wright (NINDS)

5:15 pm – 5:30 pm Recap and Closing Remarks for Day 1
David Wholley (FNIH)

5:30 pm – 6:30 pm Networking Reception



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December 13th

WEBEX TO BE ADDED

Meeting number (access code):

Meeting password:

- | | |
|----------------------------|---|
| 7:30 am – 8:00 am | Registration and Breakfast |
| 8:00 am – 8:15 am | Welcome and Introduction to Day 2
<i>David Wholley (FNIH)</i> |
| 8:15 pm – 12:30 pm | Focus Area B: Development of New Pain Medications Working Groups |
| 8:15 am – 10:15 am | Biomarkers Working Group
<i>Co-Chairs - Mark Mintun (Lilly), David Thomas (NIDA)</i> |
| 10:15 am – 10:30 am | Break |
| 10:30 am – 12:30 pm | Data Sharing Working Group
<i>Co-Chairs - John Dunlop (Amgen), Michael Oshinsky (NINDS)</i> |
| 12:30 pm – 1:15 pm | Lunch |
| 1:15 pm – 3:00 pm | Focus Area B: Refinement and Budgeting
<i>All Attendees</i> |
| 3:00 pm – 3:15 pm | Focus Area B: Next Steps and Timelines for White Paper Development
<i>David Wholley (FNIH)</i> |
| 3:15 pm – 4:00 pm | Closing Remarks |
| 3:15 pm – 3:30 pm | Summary of Focus Area A
<i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i> |



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Agenda

3:30 pm – 3:45 pm Summary of Focus Area B
Walter Koroshetz (NINDS) [David Wholley (FNIH)]

3:45 pm – 4:00 pm Closing Remarks
Francis Collins (NIH)

4:00 pm Adjourn

DRAFT

From: Wholley, David (FNIH) [T]
Sent: Mon, 4 Dec 2017 17:02:43 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: note to Janet Woodcock

After I get off the latest opioid call, sure

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 4, 2017 11:48 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: note to Janet Woodcock

Will do. In a total crunch today, can you send me a draft message that I could quickly edit and send off?

From: Wholley, David (FNIH) [T]
Sent: Monday, December 04, 2017 11:42 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: note to Janet Woodcock

Francis, you asked me to remind you to reach out to Janet today regarding FDA attendance at the face to face opioids partnership meeting on December 12-13, since we have not heard back definitively from Sharon Hertz about who will attend on those dates. As a heads up/reminder: 1) FDA has had a representative on 7 of the 9 Working Group calls we have had to date, which is pretty good 2) the main issue is December 12, when FDA has its own meeting on safe packaging for opioids 3) Sharon did say she'd find someone, it just can't be her or Ellen Fields or Doug Throckmorton, and has not said who yet. Therefore, I would probably soft shoe this a bit with Janet rather than complain we don't have anyone—you understand there is an important meeting that day, FDA challenged to find people to come on the 12th, perhaps Janet would like to attend herself since you will be there... etc.

Thanks, David

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David Wholley

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From: Wholley, David (FNIH) [T]
Sent: Mon, 4 Dec 2017 17:23:02 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: note to Janet Woodcock

For what? No problem!

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, December 4, 2017 12:11 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: note to Janet Woodcock

Sorry!

From: Wholley, David (FNIH) [T]
Sent: Monday, December 04, 2017 12:03 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: note to Janet Woodcock

After I get off the latest opioid call, sure

From: Collins, Francis (NIH/OD) [E]
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From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Sep 2017 15:16:34 +0000
To: Volkow, Nora (NIH/NIDA) [E]; Collins, Francis (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]; Boyle, Maureen (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Wilder, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]
Subject: RE: Notes and Follow up: 8-31-2017 opioid and pain meeting

Ok, thanks Nora.

(b) (4)

(b) (4)

(b) (4) Etc, etc –if you know enough at this point of course...

David Wholley
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(301) 594-6343
fnih.org

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From: Volkow, Nora (NIH/NIDA) [E]
Sent: Tuesday, September 05, 2017 10:03 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); Boyle, Maureen (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wilder, Elizabeth (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6)
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

David: thanks for feedback I modified the slides to give examples of de-risking activities. nora

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Monday, September 4, 2017 at 10:34 PM
To: Nora Volkow (b) (6), Francis Collins (b) (6)
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6), Mauree Boyle (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6), Walter Koroshetz (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), Jack Stein (b) (6), "Wilder, Elizabeth (NIH/OD) [E]" (b) (6)

(b) (6), "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Porter, Linda (NIH/NINDS) [E]" (b) (6)

Subject: RE: Notes and Follow up: 8-31-2017 opioid and pain meeting

Hi Nora, these look super. The NYT article (deaths up 22% in a year!) could not have been more unfortunate and more timely. My only suggestion would be to try to be as specific as you can on what you are seeking from the pharma partners—"de-risking" on slides 6 and 7 can mean many things.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnihi.org

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From: Volkow, Nora (NIH/NIDA) [E]
Sent: Monday, September 04, 2017 12:50 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] <(b) (6)> Volkow, Nora (NIH/NIDA) [E] (b) (6); Boyle, Maureen (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wilder, Elizabeth (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Porter, Linda (NIH/NINDS) [E] (b) (6)
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

Francis: Enclosed are my slides for the 9/7 presentation. The draft for the structure of pilot studies will take me longer to develop since we need to gather relevant information, which is not easily available.
nora

From: "Baker, Rebecca (NIH/OD) [E]" (b) (6) >
Date: Friday, September 1, 2017 at 4:08 PM
To: Francis Collins (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), Nora Volkow (b) (6), Walter Koroshetz (b) (6), Jack Stein (b) (6), "Porter, Linda (NIH/NINDS) [E]" (b) (6), "Wilder, Elizabeth (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>, "Wolinetz, Carrie (NIH/OD) [E]" (b) (6)

Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)

Subject: Notes and Follow up: 8-31-2017 opioid and pain meeting

Good afternoon,

Please find attached notes from yesterday's pain and opioid initiative planning meeting.
I've also attached the most recent table tracking participation for the September 7 and 11 meetings.
Action items from the meeting are listed below.

Actions:

(b) (4)

Thanks and wishing everyone a terrific long weekend!

Rebecca

From: Baker, Rebecca (NIH/OD) [E]

Sent: Wednesday, August 30, 2017 5:40 PM

To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6); Wilder, Elizabeth (NIH/OD) [E] (b) (6);
Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E]
(b) (6)

Cc: Boyle, Maureen (NIH/NIDA) [E] (b) (6); Schwetz, Tara (NIH/OD) [E]
(b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6);
NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke, Hilda (NIH/NIDA) [E]
(b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6); Hardesty, Rebecca
(NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>;
Stevenson, Maggie (NIH/NIDA) [E] (b) (6)

Subject: meeting materials: tomorrow's 8-31-2017 opioid and pain meeting

Good afternoon,

Please find attached materials for tomorrow's 3:30 pm meeting to discuss the NIH opioid and pain initiative.
The meeting will be held in Building 1/Room 116.

Please let me know if you have any questions:

Thank you,

Rebecca

Rebecca Baker, Ph.D.
Science Policy Analyst
Office of the Director
National Institutes of Health
Bethesda, MD 20892
Phone: (b) (6)
(b) (6)

From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Sep 2017 02:34:55 +0000
To: Volkow, Nora (NIH/NIDA) [E]; Collins, Francis (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]; Boyle, Maureen (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Wilder, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]
Subject: RE: Notes and Follow up: 8-31-2017 opioid and pain meeting

Hi Nora, these look super. The NYT article (deaths up 22% in a year!) could not have been more unfortunate and more timely. My only suggestion would be to try to be as specific as you can on what you are seeking from the pharma partners—"de-risking" on slides 6 and 7 can mean many things.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Monday, September 04, 2017 12:50 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Boyle, Maureen (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] <jack.stein@nih.gov>; Wilder, Elizabeth (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Porter, Linda (NIH/NINDS) [E] (b) (6)
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

Francis: Enclosed are my slides for the 9/7 presentation. The draft for the structure of pilot studies will take me longer to develop since we need to gather relevant information, which is not easily available.
nora

From: "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Date: Friday, September 1, 2017 at 4:08 PM
To: Francis Collins (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), Nora Volkow (b) (6), Walter Koroshetz

(b) (6), Jack Stein (b) (6)>, "Porter, Linda (NIH/NINDS) [E]"
(b) (6), "Wilder, Elizabeth (NIH/OD) [E]" (b) (6), "Wholley,
David (FNIH) [T]" <dwholley@fnih.org>, "Wolinetz, Carrie (NIH/OD) [E]"

(b) (6)
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)

Subject: Notes and Follow up: 8-31-2017 opioid and pain meeting

Good afternoon,

Please find attached notes from yesterday's pain and opioid initiative planning meeting.
I've also attached the most recent table tracking participation for the September 7 and 11 meetings.
Action items from the meeting are listed below.

Actions:

(b) (4)

Thanks and wishing everyone a terrific long weekend!

Rebecca

From: Baker, Rebecca (NIH/OD) [E]

Sent: Wednesday, August 30, 2017 5:40 PM

To: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Porter,
Linda (NIH/NINDS) [E] (b) (6); Wilder, Elizabeth (NIH/OD) [E] (b) (6)
Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E]

(b) (6)
Cc: Boyle, Maureen (NIH/NIDA) [E] (b) (6) Schwetz, Tara (NIH/OD) [E]
(b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6);
NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke, Hilda (NIH/NIDA) [E]
(b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6); Hardesty, Rebecca
(NIH/OD) [C] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>;
Stevenson, Maggie (NIH/NIDA) [E] (b) (6)>

Subject: meeting materials: tomorrow's 8-31-2017 opioid and pain meeting

Good afternoon,

Please find attached materials for tomorrow's 3:30 pm meeting to discuss the NIH opioid and pain initiative.

The meeting will be held in Building 1/Room 116.

Please let me know if you have any questions.

Thank you,

Rebecca

Rebecca Baker, Ph.D.
Science Policy Analyst
Office of the Director
National Institutes of Health
Bethesda, MD 20892
Phone (b) (6)
(b) (6)

From: Wholley, David (FNIH) [T]
Sent: Tue, 5 Sep 2017 16:12:41 +0000
To: Volkow, Nora (NIH/NIDA) [E]; Collins, Francis (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]; Boyle, Maureen (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Wilder, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

Ok sounds good.

Sent from my BlackBerry 10 smartphone.

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Tuesday, September 5, 2017 11:24 AM
To: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]; Boyle, Maureen (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Wilder, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

David

(b) (4)

(b) (4)

(b) (4). nora

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Tuesday, September 5, 2017 at 11:16 AM
To: Nora Volkow (b) (6)>, Francis Collins (b) (6)
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)>, Mauree Boyle (b) (6) "Baker, Rebecca (NIH/OD) [E]" (b) (6) Walter Koroshetz (b) (6)>, "Tabak, Lawrence (NIH/OD) [E]" (b) (6)>, Jack Stein (b) (6)>, "Wilder, Elizabeth (NIH/OD) [E]" (b) (6), "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Porter, Linda (NIH/NINDS) [E]" (b) (6)
Subject: RE: Notes and Follow up: 8-31-2017 opioid and pain meeting

Ok, thanks Nora.

(b) (4)

(b) (4)

(b) (4) Etc, etc –if you know enough at this point of course...

David Wholley
Director, Research Partnerships

Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Tuesday, September 05, 2017 10:03 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); Boyle, Maureen (NIH/NIDA) [E]
(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wilder, Elizabeth (NIH/OD)
[E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Porter, Linda
(NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6)
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

David: thanks for feedback I modified the slides to give examples of de-risking activities. nora

From: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>
Date: Monday, September 4, 2017 at 10:34 PM
To: Nora Volkow (b) (6), Francis Collins (b) (6)
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6); Mauree Boyle
(b) (6); "Baker, Rebecca (NIH/OD) [E]" (b) (6); Walter
Koroshetz (b) (6); "Tabak, Lawrence (NIH/OD) [E]"
(b) (6); Jack Stein (b) (6); "Wilder, Elizabeth (NIH/OD) [E]"
(b) (6); "Wolinetz, Carrie (NIH/OD) [E]" (b) (6); "Porter,
Linda (NIH/NINDS) [E]" (b) (6)
Subject: RE: Notes and Follow up: 8-31-2017 opioid and pain meeting

Hi Nora, these look super. The NYT article (deaths up 22% in a year!) could not have been more unfortunate and more timely. My only suggestion would be to try to be as specific as you can on what you are seeking from the pharma partners—"de-risking" on slides 6 and 7 can mean many things.

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From: Volkow, Nora (NIH/NIDA) [E]
Sent: Monday, September 04, 2017 12:50 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Schwetz, Tara (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E]
(b) (6); Boyle, Maureen (NIH/NIDA) [E] (b) (6) Baker, Rebecca
(NIH/OD) [E] <rebecca.baker@nih.gov>; Koroshetz, Walter (NIH/NINDS) [E]
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack
(NIH/NIDA) [E] (b) (6) Wilder, Elizabeth (NIH/OD) [E] (b) (6); Wolinetz,
Carrie (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Porter,
Linda (NIH/NINDS) [E] <(b) (6)>
Subject: Re: Notes and Follow up: 8-31-2017 opioid and pain meeting

Francis: Enclosed are my slides for the 9/7 presentation. The draft for the structure of pilot studies will take me longer to develop since we need to gather relevant information, which is not easily available.
nora

From: "Baker, Rebecca (NIH/OD) [E]" <rebecca.baker@nih.gov>
Date: Friday, September 1, 2017 at 4:08 PM
To: Francis Collins (b) (6), "Tabak, Lawrence (NIH/OD) [E]"
(b) (6), Nora Volkow (b) (6)>, Walter Koroshetz
(b) (6), Jack Stein (b) (6) "Porter, Linda (NIH/NINDS) [E]"
(b) (6), "Wilder, Elizabeth (NIH/OD) [E]" (b) (6), "Wholley,
David (FNIH) [T]" <(b) (6)> "Wolinetz, Carrie (NIH/OD) [E]"
(b) (6)
Cc: "Schwetz, Tara (NIH/OD) [E]" (b) (6)
Subject: Notes and Follow up: 8-31-2017 opioid and pain meeting

Good afternoon,

Please find attached notes from yesterday's pain and opioid initiative planning meeting.
I've also attached the most recent table tracking participation for the September 7 and 11 meetings.
Action items from the meeting are listed below.

Actions:

(b) (4)



(b) (4)

Thanks and wishing everyone a terrific long weekend!

Rebecca

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, August 30, 2017 5:40 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] <(b) (6)>; Porter,
Linda (NIH/NINDS) [E] (b) (6); Wilder, Elizabeth (NIH/OD) [E] (b) (6);
Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E]
(b) (6)
Cc: Boyle, Maureen (NIH/NIDA) [E] <(b) (6)>; Schwetz, Tara (NIH/OD) [E]
(b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6);
NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Schulke, Hilda (NIH/NIDA) [E]
(b) (6); Walker, Paula (NIH/NINDS) [E] <(b) (6)>; Hardesty, Rebecca
(NIH/OD) [C] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>;
Stevenson, Maggie (NIH/NIDA) [E] (b) (6)
Subject: meeting materials: tomorrow's 8-31-2017 opioid and pain meeting

Good afternoon,

Please find attached materials for tomorrow's 3:30 pm meeting to discuss the NIH opioid and pain initiative.

The meeting will be held in Building 1/Room 116.

Please let me know if you have any questions.

Thank you,

Rebecca

Rebecca Baker, Ph.D.
Science Policy Analyst
Office of the Director
National Institutes of Health
Bethesda, MD 20892
Phone: 301-402-1994

(b) (6)

From: Wholley, David (FNIH) [T]
Sent: Sun, 15 Oct 2017 15:24:06 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]
Cc: Burklow, John (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Notes and Follow up: Friday's 5pm pain and opioids meeting

In action items below, please note that my specific requests was for 4-5 academic representatives. On NIH and industry participants I am not looking for representatives but NIH's recommendations on project leads who can act as co-chairs for the design effort. Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Sunday, October 15, 2017 10:47 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Burklow, John (NIH/OD) [E] (b) (6)
Subject: Notes and Follow up: Friday's 5pm pain and opioids meeting

Good morning,

Attached please find notes from Friday's meeting to discuss the pain and opioid partnership. Action items are also listed below.

Wishing everyone a great Sunday,

Rebecca

(b) (4)

From: Baker, Rebecca (NIH/OD) [E]
Sent: Friday, October 13, 2017 12:27 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E]
(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>; Volkow, Nora
(NIH/NIDA) [E] <(b) (6)>; Koroshetz, Walter (NIH/NINDS) [E]
(b) (6); Porter, Linda (NIH/NINDS) [E] <(b) (6)>; Stein, Jack
(NIH/NIDA) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Wood, Gretchen (NIH/OD) [E]
(b) (6); Walker, Paula (NIH/NINDS) [E] <(b) (6)>; Schulke, Hilda
(NIH/NIDA) [E] (b) (6); Johnson, Ellie (NIH/NIDA) [E] (b) (6)
Subject: Materials for today's 5pm pain and opioids meeting

Good afternoon,

Materials for today's 5 pm meeting to discuss the partnership on pain and opioids are attached.
We will gather in Building 1/Room 116, and teleconference information is below:

Dial In: (b) (6); PC: (b) (6)

I will bring hard copies of all materials.

Thanks,
Rebecca

Rebecca Baker, Ph.D.
Science Policy Analyst
Office of the Director
National Institutes of Health
Bethesda, MD 20892
Phone: (b) (6)
(b) (6)

From: Wholley, David (FNIH) [T]
Sent: Tue, 7 Nov 2017 15:43:24 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Notes and follow up: Last week's opioid meetings
Attachments: Notes_Opioid and Pain PPP Meeting 11-2-2017dwrev.docx, Notes_Opioid and Pain PPP Meeting 11-3-2017dwrev.docx, Partnership Precip for PhRMA Board 11-6-2017 v2dwrev.docx

Rebecca, thanks for these notes. The strawman precis looks especially good. Attached are my redlined suggested changes and questions on the documents. As for the action items below, I believe we discussed a range of dates from Dec 11 to the 13th for the F2F, with two days being chosen depending on people's schedules—and it turns out that Francis and Walter are most available on Dec 11 and 12, so we are moving ahead with those dates. If that is incorrect please let me know immediately. I think there is also some confusion on what groups I am convening when. In my recollection, for Focus Area 2 (pain) we agreed with the plan to convene the individual working groups in data sharing, biomarkers, and clinical trials—not the “full group of private sector partners” --and share the output of those conversations prior to Dec 4 to help refine the document. There was no plan (and no time) for an additional effort to gather all the partners to discuss all these things before Dec. 4. Bill and I were to work over the weekend to lay out a template of what the 5-6 page “business case” for the pharma leaders would need to include (and yes, we did start on this, ball is currently in Bill's court).

One further question: are the results of the survey to the companies sent out after the Oct 20 call (the ones with the 17 columns and the H-M-L ratings) to be considered confidential? Or can I share these with my group co-chairs and beyond?

Thanks, David

From: Baker, Rebecca (NIH/OD) [E]
Sent: Tuesday, November 7, 2017 1:01 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Stein, Jack (NIH/NIDA) [E] (b) (6)
Subject: Notes and follow up: Last week's opioid meetings

Good evening,

In follow-up to our discussions last week on the PPP to address the opioid crisis, please find attached:

1. Notes from our standing meeting on Thursday 11-2-2017
2. Notes from our special meeting with Bill Chin on Thursday 11-3-2017
3. A draft 5-page summary of the partnership, to be further developed by NIH, PhRMA and industry leads before sharing with members of the PhRMA board on 12-4-2017. The document's substance was gathered from our many workshops this Summer and Fall, and revised by NINDS

and NIDA today. In addition, Bill Chin provided a few more parameters -- Nora, Walter, Linda and Jack, please review again and add provisional implementation plans in the new placeholder sections.

Action items are listed below:



David and I are working with Bill to keep him in the loop.

Please let me know if you have any questions.

Thanks,
Rebecca

From: Wholley, David (FNIH) [T]
Sent: Mon, 4 Dec 2017 21:25:19 +0000
To: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Biarnes, Michael (FNIH) [T]
Cc: Volkow, Nora (NIH/NIDA) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Notes and Follow up: Opioids and Pain Partnership Meeting

Carrie, we are trying for a an early draft of slides—or at least an outline thereof—in time for the co-chairs call on Thursday. I anticipate lots of additional material that needs to be filled in, reviewed by more than a few parties, and revised. I expect a final draft of slides to go out no sooner than the day before the meeting, Monday December 11.
David

From: Wolinetz, Carrie (NIH/OD) [E]
Sent: Monday, December 4, 2017 4:10 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)>; Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Cc: Volkow, Nora (NIH/NIDA) [E] (b) (6)
Subject: Re: Notes and Follow up: Opioids and Pain Partnership Meeting

Hi David,

Thanks for the follow up with the white paper outline.

I believe on the call last week you mentioned that you'd be working up to the wire on materials for next week's face to face, but in thinking about maximizing the time at the meeting - especially now that I'm looking at this ambitious outline - it seems like it would be pretty critical to share as much as possible in advance. What is the timeline that you're planning on getting materials out? Is before the weekend feasible? Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health

(b) (6)

----- Original message -----

From: "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Date: 12/1/17 10:42 AM (GMT-05:00)

To: "Collins, Francis (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]"
(b) (6) Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Koroshetz,
Walter (NIH/NINDS) [E]" (b) (6), "Porter, Linda (NIH/NINDS) [E]"
(b) (6) "Stein, Jack (NIH/NIDA) [E]" (b) (6), "Wholley, David (FNIH) [T]"
<dwholley@fnihi.org>, "Biarnes, Michael (FNIH) [T]" <mbiarnes@fnihi.org>
Cc: "Volkow, Nora (NIH/NIDA) [E]" (b) (6)
Subject: Notes and Follow up: Opioids and Pain Partnership Meeting

Good morning,

Attached please find notes and action items from yesterday's pain and opioid meeting. I've also attached an electronic copy of the first-pass of the integrated agenda for Dec 12-13 distributed at the meeting.

Action items are also listed below.



Please let me know if you have any questions or concerns.

Thanks,
Rebecca

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, November 29, 2017 5:17 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Wolinetz, Carrie (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]
(b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack
(NIH/NIDA) [E] <(b) (6)>; Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: McManus, Ayanna (NIH/OD) [E] <(b) (6)>; NIHDirectorMeetings
<NIHDirectorMeetings@mail.nih.gov>
Subject: Materials for tomorrow's Opioids and Pain Partnership Meeting

Good afternoon,

Please find attached materials for tomorrow's opioid and pain partnership discussion. We will gather in 1/116. Attachments are also listed below:

Attachment 1 – Notes from conversations with PhRMA

Attachment 2 -- Draft 5-pager for PhRMA

Attachment 3 – Agenda for Dec 11 NIDA/ECRI meeting

Attachment 4 – Agenda for Dec 12-13 face-to-face partnership meeting

Thanks and see you tomorrow,

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Thu, 19 Oct 2017 02:53:45 +0000
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: Re: New PPPs for pain meds and OUD treatment

Yes, and is he ok with inviting them to call on Friday (he should be--lets just make sure no issues)

Sent from my BlackBerry 10 smartphone.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Wednesday, October 18, 2017 10:32 PM
To: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: RE: New PPPs for pain meds and OUD treatment

Happy to inform Bill – the news is that Ellen, Celia and Allison will serve as FDA liaisons?

Thanks,
Rebecca

From: Wholley, David (FNIH) [T]
Sent: Wednesday, October 18, 2017 5:24 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: FW: New PPPs for pain meds and OUD treatment

All: As promised from my conversation on Monday with Janet Woodcock. Should these folks be invited to Friday's call? If so, should Rebecca be the one to let Bill Chin know? Thanks, David

David Wholley
Director, Research Partnerships
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(301) 594-6343
fnih.org

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From: Hertz, Sharon H (b) (6)
Sent: Wednesday, October 18, 2017 4:59 PM
To: Wholley, David (FNIH) [T] (b) (6)
Cc: Winchell, Celia J (FDA/CDER) (b) (6); Fields, Ellen (FDA/CDER) (b) (6)
Subject: New PPPs for pain meds and OUD treatment

Hi,

After discussing this with Dr. Woodcock, I am reaching out to let you know that Ellen Fields will be participating as the primary representative for the new pain meds PPP and Celia Winchell for the OUD treatment PPP. Allison Lin will also be participating from our division.

Thank you,
Sharon

Sharon Hertz, MD
Division Director
Division of Anesthesia, Analgesia, and Addiction Products
FDA/CDER
HFD-170, WO 22, Rm (b) (6)
10903 New Hampshire Ave.
Silver Spring, MD 20993

(b) (6)

(b) (6) Fax

From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 21:02:50 +0000
To: Chin, Bill; Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Pritchett, Anne; Koch, Kellie
Subject: RE: Next Steps

Hi Bill, glad to talk. How best to reach you?

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, October 10, 2017 3:11 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Pritchett, Anne <APritchett@phrma.org>; Koch, Kellie <KKoch@phrma.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Next Steps

Francis, This makes perfect sense especially thinking about an announcement sooner rather than later. I'll call David to ask how we can help, for instance, to assure timely responses, etc from representatives of our member companies while we really have their attention. Also, I can update him on the PhRMA contribution to the planning effort [we just need Maria's signature and we'll turn around the payment immediately] with a focus on additional \$\$\$ ☺ Bill

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Tuesday, October 10, 2017 12:24 PM
To: Chin, Bill
Cc: Baker, Rebecca (NIH/OD) [E]; Pritchett, Anne
Subject: RE: Next Steps

Hi Bill,

Sure, I'll suggest to David W. that you speak directly with him.

My own ideas here: Establishing leadership of the workstreams, and doing the due diligence consultations, is the most important first step, and we can get started immediately with those activities. That will show the companies that something is happening. David predicts (and I think he has a lot of experience here) that the F2F meeting won't be terribly successful unless those consultations are done first.

None of this says we can't have a public announcement sooner, if that seems to be merited.

Francis

From: Chin, Bill [<mailto:Chin@phrma.org>]
Sent: Tuesday, October 10, 2017 10:44 AM
To: Pritchett, Anne <APritchett@phrma.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)>
Cc: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Next Steps

Of course, I agree with Anne's comments, especially regarding the important need to balance the work flow with the urgency. That said, I truly believe that 6 weeks is too long with due respect to David W. As I have stepped down from my position at PhRMA today, may I'd like to offer any help to expedite the matter. In any case, putting a stake in the ground about the date of the first F2F is important. May I suggest that I speak to David W directly to chat about options? In the meantime, I will be sending the signed agreement for the planning phase today. Bill

From: Pritchett, Anne
Sent: Tuesday, October 10, 2017 9:18 AM
To: Baker, Rebecca (NIH/OD) [E]; Chin, Bill
Cc: Collins, Francis (NIH/OD) [E]
Subject: RE: Next Steps

Francis and Rebecca,

Thank you again for the opportunity to speak on Friday. We appreciate the follow up. 6 weeks sounds very long given you'd previously indicated early Dec. for an action plan. On question I have is whether the WH is going to want to say something on the PPP in conjunction with the release of the Pres. Commission report in Nov.—if you can get better sense re. their expectations that would be helpful. I would think at a minimum we'd collectively want to indicate we have a meeting scheduled but again worried that could be interpreted as lack of urgency. We'd appreciate your thoughts on how to navigate that.

We are receiving a high level of inquiries from companies as we'd collectively communicated sense of urgency around this. The sooner we can outline a timeline of meetings/calls with sense of milestones and deliverables over the next few months that we can communicate to those who have agreed to participate and to our Board that would be very helpful and assist participants in planning. Please let us know whether and how we can assist on that front.

We fully agree regarding the need not to lose momentum, Anne

From: Baker, Rebecca (NIH/OD) [E] (b) (6)
Sent: Tuesday, October 10, 2017 7:51 AM
To: Chin, Bill
Cc: Collins, Francis (NIH/OD) [E]; Pritchett, Anne
Subject: Re: Next Steps

Dear Bill,

Thanks again for taking the time to talk with us Friday.

It is important that we keep in communication as this initiative has so many components yet to be defined, and changes so quickly.

We agree on the need to move swiftly on our next action.

We met with our internal team Friday to discuss next steps for planning the partnership. The consensus was some additional work would need to take place before the convening of the first face-to-face meeting. Specifically, we will need to hold preparatory conference calls with participants, and brief NIH and industry co-chairs for each of the partnership work-streams.

On one hand, it would be very ambitious to accomplish all this preparatory work in three weeks. On the other, if we wait too long, we lose momentum and valuable time in this crisis.

On David's advice, we are now thinking about a face-to-face meeting in approximately 6 weeks. Francis has checked with Reed Cordish, and the White House preference would be to plan some sort of announcement that could coincide with that meeting.

Would PhRMA have concerns about this timeline, and if so, what other ways could we satisfy stakeholders while still ensuring the ultimate success of the partnership?

Thanks again for working with us on these issues. We look forward to your thoughts.

Best,

Rebecca

On Oct 9, 2017, at 2:32 PM, Chin, Bill <Chin@phrma.org> wrote:

Rebecca and Francis, Thanks for our call on Friday. I've had a discussion with Steve and the management committee this morning. We agree with your suggestion to delay any press release in order to synchronize with the WH need to have announcement in the next several weeks. However, we agree that we should plan for the first PPP planning meetings in the next weeks or so. In fact, we ideally would like to let our Board know about such plan this Wednesday as many member companies are asking Anne and me about next steps. Did you learn enough you meeting with David W and the FNIH on Friday afternoon to proceed very soon, or at least to put a stake in the ground and name a date? As we discussed, this could be a back-to-back meetings on PPP#1 and PPP#2 with a short overlap session a la Keystone meetings, etc. I'm available for a chat anytime. Bill

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Oct 2017 13:54:22 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]
Subject: Re: NINDS action items from friday

I can speak late this afternoon if you wish Walter.
Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Monday, October 16, 2017 9:32 AM
To: Wholley, David (FNIH) [T]; Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]
Subject: RE: NINDS action items from friday

Might discuss. [REDACTED] (b) (5)
w

From: Wholley, David (FNIH) [T]
Sent: Sunday, October 15, 2017 9:12 PM
To: Porter, Linda (NIH/NINDS) [E] [REDACTED] (b) (6); Baker, Rebecca (NIH/OD) [E]
[REDACTED] (b) (6); Tabak, Lawrence (NIH/OD) [E] [REDACTED] (b) (6); Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6); Wolinetz, Carrie (NIH/OD) [E] [REDACTED] (b) (6); Volkow, Nora (NIH/NIDA) [E] <[REDACTED] (b) (6)>; Koroshetz, Walter (NIH/NINDS) [E]
[REDACTED] (b) (6); Stein, Jack (NIH/NIDA) [E] [REDACTED] (b) (6)
Cc: Burklow, John (NIH/OD) [E] [REDACTED] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>
Subject: RE: NINDS action items from friday

Hi, Linda, thanks for sending this. [REDACTED] (b) (5)
[REDACTED] (b) (5)
[REDACTED] (b) (5) thanks

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From: Porter, Linda (NIH/NINDS) [E]
Sent: Sunday, October 15, 2017 6:08 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E]
[REDACTED] (b) (6); Tabak, Lawrence (NIH/OD) [E] [REDACTED] (b) (6); Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6); Wolinetz, Carrie (NIH/OD) [E] [REDACTED] (b) (6); Volkow,

Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]
(b) (6) Stein, Jack (NIH/NIDA) [E] (b) (6)
Cc: Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T]
<mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: NINDS action items from friday

Walter and I made contact and here is the list of recommendations

(b) (5)



Linda

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Oct 2017 01:11:50 +0000
To: Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]
Cc: Burklow, John (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: NINDS action items from friday

Hi, Linda, thanks for sending this. (b) (5)

(b) (5) thanks

David Wholley
Director, Research Partnerships
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(301) 594-6343
fnih.org

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From: Porter, Linda (NIH/NINDS) [E]
Sent: Sunday, October 15, 2017 6:08 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)>; Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)>; Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6)>; Stein, Jack (NIH/NIDA) [E] (b) (6)
Cc: Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: NINDS action items from friday

Walter and I made contact and here is the list of recommendations

(b) (5)

(b) (5)

Linda

From: Wholley, David (FNIH) [T]
Sent: Tue, 17 Oct 2017 18:50:32 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Burklow, John (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Johnson, Ellie (NIH/NIDA) [E]
Subject: RE: NINDS action items from friday

(b) (5)

David Wholley
Director, Research Partnerships
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From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Tuesday, October 17, 2017 2:48 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6)
Subject: RE: NINDS action items from friday

(b) (5)

walter

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 17, 2017 6:47 AM
To: Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Johnson, Ellie (NIH/NIDA) [E]

(b) (6)

Subject: RE: NINDS action items from friday

Looks reasonable to me. Presentations must be really concise, don't want to compromise the discussion time. As with prior iterations of this plan, it would be good to prime a few participants to start the discussion so that there are not crickets when we get to that part.

FC

From: Baker, Rebecca (NIH/OD) [E]

Sent: Monday, October 16, 2017 6:09 PM

To: Volkow, Nora (NIH/NIDA) [E] (b) (6) Porter, Linda (NIH/NINDS) [E]

(b) (6)

Cc: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Tabak, Lawrence (NIH/OD) [E]

(b) (6);

Collins, Francis (NIH/OD) [E] (b) (6) Wolinetz, Carrie

(NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]

(b) (6);

Stein, Jack (NIH/NIDA) [E] (b) (6) Burklow, John (NIH/OD)

[E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Menetski, Joseph (FNIH)

[T] <jmenetski@fnihi.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6)

Subject: RE: NINDS action items from friday

Nora, to facilitate discussion, and based on our call this afternoon, I developed a draft agenda (attached).

Others please feel free to weigh in.

Thanks,
Rebecca

From: Volkow, Nora (NIH/NIDA) [E]

Sent: Monday, October 16, 2017 4:28 PM

To: Porter, Linda (NIH/NINDS) [E] (b) (6)

Cc: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E]

(b) (6);

Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis

(NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6)

Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E]

(b) (6);

Burklow, John (NIH/OD) [E] (b) (6) Biarnes, Michael (FNIH) [T]

(b) (6);

Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Johnson, Ellie (NIH/NIDA) [E]

(b) (6)

Subject: Re: NINDS action items from friday

David and Walter. I am on meetings until 8 pm. Could we speak on the phone later tonight perhaps 8:30; to touch base since we have such limited time to organize this. Nora

Sent from my iPhone

On Oct 16, 2017, at 4:07 PM, Porter, Linda (NIH/NINDS) [E] (b) (6) wrote:

David

A few changes from our follow-up emails

From: Porter, Linda (NIH/NINDS) [E]

Sent: Sunday, October 15, 2017 6:08 PM

To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]

(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)

Cc: Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>

Subject: NINDS action items from friday

Walter and I made contact and here is the list of recommendations

(b) (5)

Linda

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Dec 2017 13:12:54 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]
Subject: RE: Opioid PPP update for BMAC 12-19-17 integrated clean

Thanks, everyone!

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, December 21, 2017 7:25 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: RE: Opioid PPP update for BMAC 12-19-17 integrated clean

Looks good to me, fine to send to PhRMA now.

From: Wholley, David (FNIH) [T]
Sent: Wednesday, December 20, 2017 7:08 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)>
Subject: Opioid PPP update for BMAC 12-19-17 integrated clean

Francis, please see the attached clean final draft of the opioids section of the update on FNIH partnerships requested by the BMAC. It has been reviewed by Larry, Nora, Walter, and Rebecca and I think captures the gist of our meeting and decision process to date. Please let me know any recommended changes as soon as possible so I can send to PhRMA. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Wed, 29 Nov 2017 03:23:13 +0000
To: Volkow, Nora (NIH/NIDA) [E]
Cc: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Opioids Face-to-Face Meeting Invitation

Thanks, Nora!

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Tuesday, November 28, 2017 10:18 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Re: Opioids Face-to-Face Meeting Invitation

David. (b) (5) Nora

Sent from my iPhone

On Nov 28, 2017, at 8:10 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Hi Walter.

(b) (5)

Thanks for the feedback. David

Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Tuesday, November 28, 2017 7:03 PM
To: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie

(NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Opioids Face-to-Face Meeting Invitation

Thanks David.

(b) (5)

Walter

From: Wholley, David (FNIH) [T]
Sent: Tuesday, November 28, 2017 4:08 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>
Subject: Opioids Face-to-Face Meeting Invitation

Dear All –

This is regarding the December 12-13 face to face. Can you please see below and let us know asap:

(b) (5)

We really need your feedback asap, preferably this evening (we can send out additional invitations a bit later if needed of course). Please copy Mike Biarnes on your replies.

Thanks, David

From: Biarnes, Michael (FNIH) [T]
Sent: Monday, November 27, 2017 1:42 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>
Subject: Opioids Face-to-Face Meeting Information

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- Title of the Partnership – [REDACTED] (b) (5)
- Meeting Overview (*Suggested language below*)
- Invitation list (*compiled FA 1 and FA 2 list attached*)

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Thanks,
Mike

(b) (5)

We've moved! Please find our new address below.

Michael Biarnes

Scientific Project Manager

Foundation for the National Institutes of Health

(301) 594-2612

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Wed, 29 Nov 2017 02:10:18 +0000
To: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: Re: Opioids Face-to-Face Meeting Invitation

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(b) (5)

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Sent from my BlackBerry 10 smartphone.

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Sent: Tuesday, November 28, 2017 7:03 PM
To: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
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Thanks David.

(b) (5)

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Sent: Tuesday, November 28, 2017 4:08 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)

Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
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Sent: Monday, November 27, 2017 1:42 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
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Mike

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From: Wholley, David (FNIH) [T]
Sent: Wed, 29 Nov 2017 03:26:03 +0000
To: Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]
Cc: Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Opioids Face-to-Face Meeting Invitation

Thanks. Will wait until mid-morning tomorrow (11 am) and unless we hear any feedback to the contrary, Mike please go ahead and pull the trigger on the meeting invitation system. We are working on a preliminary agenda as well...

From: Baker, Rebecca (NIH/OD) [E]
Sent: Tuesday, November 28, 2017 10:24 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Volkow, Nora (NIH/NIDA) [E] <nvolkow@nida.nih.gov>
Cc: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Opioids Face-to-Face Meeting Invitation

I agree with the new language for the biomarkers goal and that "address the opioid crisis" is good. This title is also consistent with what we've used in previous materials.

Best,
Rebecca

From: Wholley, David (FNIH) [T]
Sent: Tuesday, November 28, 2017 10:23 PM
To: Volkow, Nora (NIH/NIDA) [E] (b) (6)
Cc: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Opioids Face-to-Face Meeting Invitation

Thanks, Nora!

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Tuesday, November 28, 2017 10:18 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]

(b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Re: Opioids Face-to-Face Meeting Invitation

David. (b) (5) Nora

Sent from my iPhone

On Nov 28, 2017, at 8:10 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

(b) (5)

Thanks for the feedback. David

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Sent: Tuesday, November 28, 2017 7:03 PM
To: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Opioids Face-to-Face Meeting Invitation

Thanks David.

(b) (5)

Walter

From: Wholley, David (FNIH) [T]
Sent: Tuesday, November 28, 2017 4:08 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,
Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
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Thanks, David

From: Biarnes, Michael (FNIH) [T]
Sent: Monday, November 27, 2017 1:42 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
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Please let me know your thoughts so that we can finalize these items and get the registration information sent out to all of the working group members.

Thanks,
Mike

(b) (5)

We've moved! Please find our new address below.

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Scientific Project Manager

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Tue, 10 Oct 2017 16:32:25 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Opioids partnership next steps

Sure.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 10, 2017 12:26 PM
To: Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: RE: Opioids partnership next steps

Hi David,

(b) (5)

Thanks, Francis

From: Wholley, David (FNIH) [T]
Sent: Friday, October 06, 2017 6:24 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: Opioids partnership next steps

Francis, as requested:

Opioid PPP – Next Steps 10/5/17

(b) (4), (b) (5)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Wholley, David (FNIH) [T]
Sent: Mon, 2 Oct 2017 21:59:12 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: RE: opioids PPP and where we go next

Hi Francis,
Yes I did hear, and like everyone am deeply shocked and saddened to hear the reason behind this delay.

Before I answer, let me please make sure that my basic assumptions are correct: (b) (5)

(b) (5)

Assuming that is true (please tell me right away if I don't have it right), (b) (5)

(b) (5)

I am happy to discuss of course at any time, including on our Thursday call. Please let me know when you think you have a complete enough list of names to begin.

David

David Wholley

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Foundation for the National Institutes of Health
(301) 594-6343
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From: Collins, Francis (NIH/OD) [E]
Sent: Monday, October 02, 2017 12:42 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora
(NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]
<koroshetzw@ninds.nih.gov>; Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda
(NIH/NINDS) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: opioids PPP and where we go next

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I guess you have heard that the White House event on opioids, tentatively planned for this coming Wednesday, has been postponed due to the POTUS's travel to Las Vegas. But the WH hasn't given up on this. Reed Cordish just called to suggest the idea of an event in about a month – to highlight NIH, FDA, and industry working together on the PPP.

More than two dozen companies have sent in names of designated hitters to serve on the groups that will be charged with putting together a workplan, timetable, and budget for projects #1 and #2. (b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Tue, 3 Oct 2017 13:49:12 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: RE: opioids PPP and where we go next

Thanks for asking, Francis.

(b) (5)

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

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From: Collins, Francis (NIH/OD) [E]
Sent: Monday, October 02, 2017 9:35 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: RE: opioids PPP and where we go next

Hi David,

I think you have the plan correctly and realistically scoped – I'm asking Nora and Walter to weigh in if they think otherwise.

What you propose for a one month time frame sounds appropriate to me, and (b) (5)

(b) (5)

FC

From: Wholley, David (FNIH) [T]

Sent: Monday, October 02, 2017 5:59 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]

(b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) Volkow, Nora
(NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]

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Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora
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(b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Sat, 9 Sep 2017 16:55:12 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Re: PACT (b) (4).

Yes, please-couldn't hurt

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, September 8, 2017 9:28 PM
To: Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]
Subject: RE: PACT (b) (4).

Hooray

(b) (4)

(b) (4)

FC

From: Wholley, David (FNIH) [T]
Sent: Friday, September 08, 2017 12:11 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: PACT (b) (4)

(b) (4)

Regards,
David

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Director, Research Partnerships
Foundation for the National Institutes of Health
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From: (b) (4)
Sent: Friday, September 08, 2017 10:51 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: Adam, Stacey (FNIH) [T] <sadam@fnihi.org> (b) (4)
Subject: Re: Checking in

(b) (4)

Sent from my iPhone

On Sep 8, 2017, at 4:19 PM, Wholley, David (FNIH) [T] <dwholley@fnihi.org> wrote:

EXTERNAL

(b) (4)

Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnihi.org

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GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

From: Wholley, David (FNIH) [T]
Sent: Tue, 7 Nov 2017 18:28:33 +0000
To: Collins, Francis (NIH/OD) [E]; Chin, Bill
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: Re: Opioid Partnership: Co-Chairing the Biomarkers Working Group

I think I am the designated contact and you can refer callers to me.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, November 7, 2017 12:33 PM
To: Chin, Bill; Wholley, David (FNIH) [T]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Wow, it seems like a lot of calls are happening to different folks. Do all of us need to get on the phone today and discuss how best to present a single perspective? It seems to me that David ought to be the main point of contact.

FC

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, November 07, 2017 10:29 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Indeed, Chris called. He is concerned about the need to have short-term "fixes" emphasized and while he is (and we are) supporters of biomarkers, he is concerned that the work stream might be viewed as a separate goal independent of the whole. David—In your call, you just need to assure him that all are connected. BTW, others whom you have contacted are also seeking to talk to me. Might we coordinate the discussions a bit? Thanks. Bill

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Cc: Chin, Bill <Chin@phrma.org>
Subject: FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group
Importance: High

Hi David,

(b) (5)

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Cc: Chin, Bill <Chin@phrma.org>
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Sent: Monday, November 06, 2017 7:52 PM
To: Flores, Christopher [CONUS] <CFlores2@its.jnj.com>
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Baker, Rebecca (NIH/OD) [E] [REDACTED] (b) (6); Thomas, David (NIH/NIDA) [E] [REDACTED] (b) (6); Mark Mintun <mintun@avidrp.com>
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We really look forward to working with you on this important endeavor.

Regards,

David Wholley

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David Wholley

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From: Wholley, David (FNIH) [T]
Sent: Tue, 7 Nov 2017 16:27:05 +0000
To: Chin, Bill; Collins, Francis (NIH/OD) [E]
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Got it. I am speaking to Chris Flores at 2:30 apparently.

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, November 7, 2017 10:54 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

David, I just want to echo your comments. I don't need to be a participant in the calls—in the spirit of speed—but would be eager to hear anything relevant, such as issues that arise, to aid the conversation.
Bill

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]
Sent: Tuesday, November 07, 2017 10:48 AM
To: Chin, Bill; Collins, Francis (NIH/OD) [E]
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Yes, Bill I will reassure him. Some of this is normal start-up anxiety I think. How would you suggest we coordinate the discussions? I have my first co-chair precall today (on clinical trials, with Verbarg and Wright) today at 3:30, in keeping with our need to move fast. David

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Subject: FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group
Importance: High

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Sent: Monday, November 06, 2017 7:52 PM

To: Flores, Christopher [CONUS] <CFlores2@its.jnj.com>

Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Thomas, David (NIH/NIDA) [E] (b) (6); Mark Mintun <mintun@avidrp.com>

Subject: Opioid Partnership: Co-Chairing the Biomarkers Working Group

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After extensive additional discussion among the sponsors, it has been decided that Nora Volkow's team at NIDA will take the lead in developing ideas for Focus Area 1 and FNIH will lead the design effort for Focus Area 2. **We would like to ask you to please co-chair the Working Group define Project 2c: Joint development of biomarkers (along with Mark Mintun of Lilly and David Thomas of NIDA) as this will no doubt be our most complex challenge.**

Given the urgency of moving forward on this initiative we have agreed on an aggressive timetable for coming up with at least an initial plan for each project that includes several 2-hour phone calls with each Working Group over the next five weeks. **We would therefore ask if you can please work with Cheryl Melencio on our staff to 1) find some times that we can schedule a 30 minute Co-Chair pre-call in the next few days (November 7-10) to agree on an approach and workplan for the Working Group and 2) a list of times that would work best for you to participate in at least the first 2-hour call sometime between the end of next week and the end of the following week (November 10-17).** Please copy Cheryl Melencio and Mike Biarnes on your response. We will set up future calls in parallel with setting up our pre-call discussions with you.

We really look forward to working with you on this important endeavor.

Regards,

David Wholley

We've moved! Please find our new address below.

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Tue, 7 Nov 2017 19:22:31 +0000
To: Chin, Bill; Collins, Francis (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

If it is about the pain stuff I am fine with calling people back. I suspect that if it is Focus Area 1 NIH will want that to go to Nora Volkow or perhaps Jack Stein, but that is their decision.

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, November 7, 2017 1:39 PM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]
(b) (6)
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

That's fine. However, the callers are often not the designated co-chairs, and want to chat in part because they feel they're in the dark. What about questions regarding MAT, repurposing, etc? Bill

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]
Sent: Tuesday, November 07, 2017 1:29 PM
To: Collins, Francis (NIH/OD) [E]; Chin, Bill
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: Re: Opioid Partnership: Co-Chairing the Biomarkers Working Group

I think I am the designated contact and you can refer callers to me.

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, November 7, 2017 12:33 PM
To: Chin, Bill; Wholley, David (FNIH) [T]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Wow, it seems like a lot of calls are happening to different folks. Do all of us need to get on the phone today and discuss how best to present a single perspective? It seems to me that David ought to be the main point of contact.

FC

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, November 07, 2017 10:29 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Indeed, Chris called. He is concerned about the need to have short-term “fixes” emphasized and while he is (and we are) supporters of biomarkers, he is concerned that the work stream might be viewed as a separate goal independent of the whole. David—In your call, you just need to assure him that all are connected. BTW, others whom you have contacted are also seeking to talk to me. Might we coordinate the discussions a bit? Thanks. Bill

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnihi.org>]
Sent: Tuesday, November 07, 2017 8:40 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Chin, Bill
Subject: RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

(b) (5)

I just opened his email and will arrange to speak to him today. David

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, November 7, 2017 8:04 AM
To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>
Cc: Chin, Bill <Chin@phrma.org>
Subject: FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group
Importance: High

Hi David,

(b) (5)

FC

From: Flores, Christopher [CONUS] [<mailto:CFlores2@its.inj.com>]
Sent: Tuesday, November 07, 2017 7:47 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Chin, Bill <Chin@phrma.org>
Subject: FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group
Importance: High

Dear Francis,

As you may be aware, I received yesterday evening the below message from David, which departs in substantial ways from the proposal you sent to Paul Stoffels last week. Notwithstanding whatever role I may play going forward, there exist for me serious concerns regarding the apparent decision to subdivide Focus Area 2. In short, based at least in part on my experience with PPP's as well as my understanding of the present initiative from having participated in multiple steps/meetings leading to this point, I believe this approach has the potential to reduce efficiency and the probability of success.

Moreover, I am concerned about the emphasis here on Project 2c, related to the development of biomarkers, which arguably has very limited potential to address the opioid crisis in the short-term; and

I've copied Bill here, as he and I spoke about this last night. Also, after receiving the below message, I immediately offered to have a call with David sometime this week, though I have not yet heard back from him.

Please let me know if you would care to discuss these concerns in greater detail. Otherwise, for the time being, I hope the opportunity still exists to formulate the execution of Focus Area 2 in a way that maximizes the potential of an NIH-PhRMA partnership to have a meaningful effect on accelerating the development of non-addictive/non-opioid analgesics.

Thank you for your consideration,
Chris

Christopher M. Flores, Ph.D.
Head, Emerging Science and Innovation Strategy
Johnson & Johnson Consumer Inc.
7050 Camp Hill Road – RA2688
Fort Washington, PA 19034
215.273.8056 (office)
(b) (6) (mobile)
cflores2@its.jnj.com
www.linkedin.com/in/chrisfloresinnovator

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"A society grows great when its elders plant trees in whose shade they know they shall never sit." - Greek Proverb

From: Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]
Sent: Monday, November 06, 2017 7:52 PM
To: Flores, Christopher [CONUS] <CFlores2@its.jnj.com>
Cc: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Thomas, David (NIH/NIDA) [E] (b) (6); Mark Mintun <mintun@avidrp.com>
Subject: Opioid Partnership: Co-Chairing the Biomarkers Working Group
Importance: High

Dear Chris:

Thank you for agreeing to help lead Working Group activities as part of our efforts to develop a public-private partnership to address the national opioid crisis. As you will recall, the partnership has decided to address two focus areas:

1. Develop new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose, and
2. Develop new non-addictive pain therapies-- with Focus Area #2 being further subdivided into three discrete projects: 2a: Share data on successful and failed drug development (with NIH as neutral broker), 2b: Create a clinical trial network to coordinate clinical testing of novel treatments, and 2c: Joint development of biomarkers.

After extensive additional discussion among the sponsors, it has been decided that Nora Volkow's team at NIDA will take the lead in developing ideas for Focus Area 1 and FNIH will lead the design effort for Focus Area 2. **We would like to ask you to please co-chair the Working Group define Project 2c: Joint development of biomarkers (along with Mark Mintun of Lilly and David Thomas of NIDA) as this will no doubt be our most complex challenge.**

Given the urgency of moving forward on this initiative we have agreed on an aggressive timetable for coming up with at least an initial plan for each project that includes several 2-hour phone calls with each Working Group over the next five weeks. **We would therefore ask if you can please work with Cheryl Melencio on our staff to 1) find some times that we can schedule a 30 minute Co-Chair pre-call in the next few days (November 7-10) to agree on an approach and workplan for the Working Group and 2) a list of times that would work best for you to participate in at least the first 2-hour call sometime between the end of next week and the end of the following week (November 10-17).** Please copy Cheryl Melencio and Mike Biarnes on your response. We will set up future calls in parallel with setting up our pre-call discussions with you.

We really look forward to working with you on this important endeavor.

Regards,

David Wholley

We've moved! Please find our new address below.

David Wholley

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T]
Sent: Mon, 23 Oct 2017 18:25:00 +0000
To: Chin, Bill
Cc: Barese, Eric (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; SRAtemp; Dolinski, Kristin; Vereshchagina, Lucy; Moscicki, Richard
Subject: Re: Opioid PPP Planning

By copy to Eric, in process. Thank you, Bill!
Sent from my BlackBerry 10 smartphone.

From: Chin, Bill
Sent: Monday, October 23, 2017 1:09 PM
To: Wholley, David (FNIH) [T]
Cc: Barese, Eric (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; SRAtemp; Dolinski, Kristin; Vereshchagina, Lucy; Moscicki, Richard
Subject: Opioid PPP Planning

David, We are prepared to provide the second tranche of the discussed \$200K support to the FNIH of the planning process for the proposed opioid PPP. Can you ask Eric to provide another LOA for the amount of \$100K to begin the process? Thanks. Bill

From: Wholley, David (FNIH) [T]
Sent: Wed, 20 Dec 2017 02:45:13 +0000
To: Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Collins, Francis (NIH/OD) [E]
Subject: RE: Opioid PPP update for BMAC 12-19-17 draft for NIH

Ok, thanks

From: Baker, Rebecca (NIH/OD) [E]
Sent: Tuesday, December 19, 2017 9:44 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: Re: Opioid PPP update for BMAC 12-19-17 draft for NIH

Thanks David,

Reading through this now, and will write back soon with thoughts on best strategy for sharing with the rest of the team.

Thanks
Rebecca

Sent from my iPhone

On Dec 19, 2017, at 7:37 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David
<Opioid PPP update for BMAC 12-19-17 draft for NIH.docx>

From: Wholley, David (FNIH) [T]
Sent: Wed, 20 Dec 2017 03:22:42 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: RE: Opioid PPP update for BMAC 12-19-17 draft for NIH

By the way, final header in the doc will read BMAC update, not (generic) "Board" Update...

From: Wholley, David (FNIH) [T]
Sent: Tuesday, December 19, 2017 7:38 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: Opioid PPP update for BMAC 12-19-17 draft for NIH

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Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Mon, 21 Aug 2017 13:00:33 +0000
To: Collins, Francis (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; NIHDirectorMeetings; Melencio, Cheryl (FNIH) [T]
Subject: Re: PACT Outreach Update -- Genentech is in

(b) (4)

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, August 21, 2017 8:47 AM
To: Wholley, David (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; NIHDirectorMeetings; Melencio, Cheryl (FNIH) [T]
Subject: RE: PACT Outreach Update -- Genentech is in

Thanks. Glad to hear about Genentech.

(b) (4)

From: Wholley, David (FNIH) [T]
Sent: Sunday, August 20, 2017 1:08 PM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: PACT Outreach Update -- Genentech is in

Dear All:

I know we have a call currently scheduled for Thursday but thought I would give you all an update now on where things stand. Biggest news is that I **received an email from Edith Perez on Friday afternoon confirming that Genentech has found the funding for PACT and will join**; Stacey and I have a follow-up call scheduled with her Thursday noontime to discuss the details. Summary, then:

YES – Abbvie, Boehringer-Ingelheim, BMS, Celgene, Genentech, Pfizer

(b) (4)

Status document (attached) has been updated to reflect all this.

Thanks,
David

From: Wholley, David (FNIH) [T]
Sent: Wed, 27 Sep 2017 21:55:38 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]
Subject: RE: PACT plan for announcement
Attachments: Updated PACT Executive Summary 092617.docx

I think this is as close to an effective 2-pager as we have, but it may need to be "HHS-ized" or merged with the summary Rebecca has already put together for HHS use. We have a meeting with you/Larry/Doug/Jim tomorrow to update on PACT, but the upshot is that I went back to our holdouts yesterday with the update that the announcement will happen on Oct 12 and we need an answer.
Results:

(b) (4)

We have also been on the phone with Renata Myles, Rebecca, and Peter Garrett from NCI Communications team to discuss the setup and comm plan for the 12th and will likely want to discuss that with you tomorrow as well (who from companies are invited, who speaks, etc.)

David

David Wholley
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From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, September 27, 2017 4:40 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]
(b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Subject: PACT plan for announcement